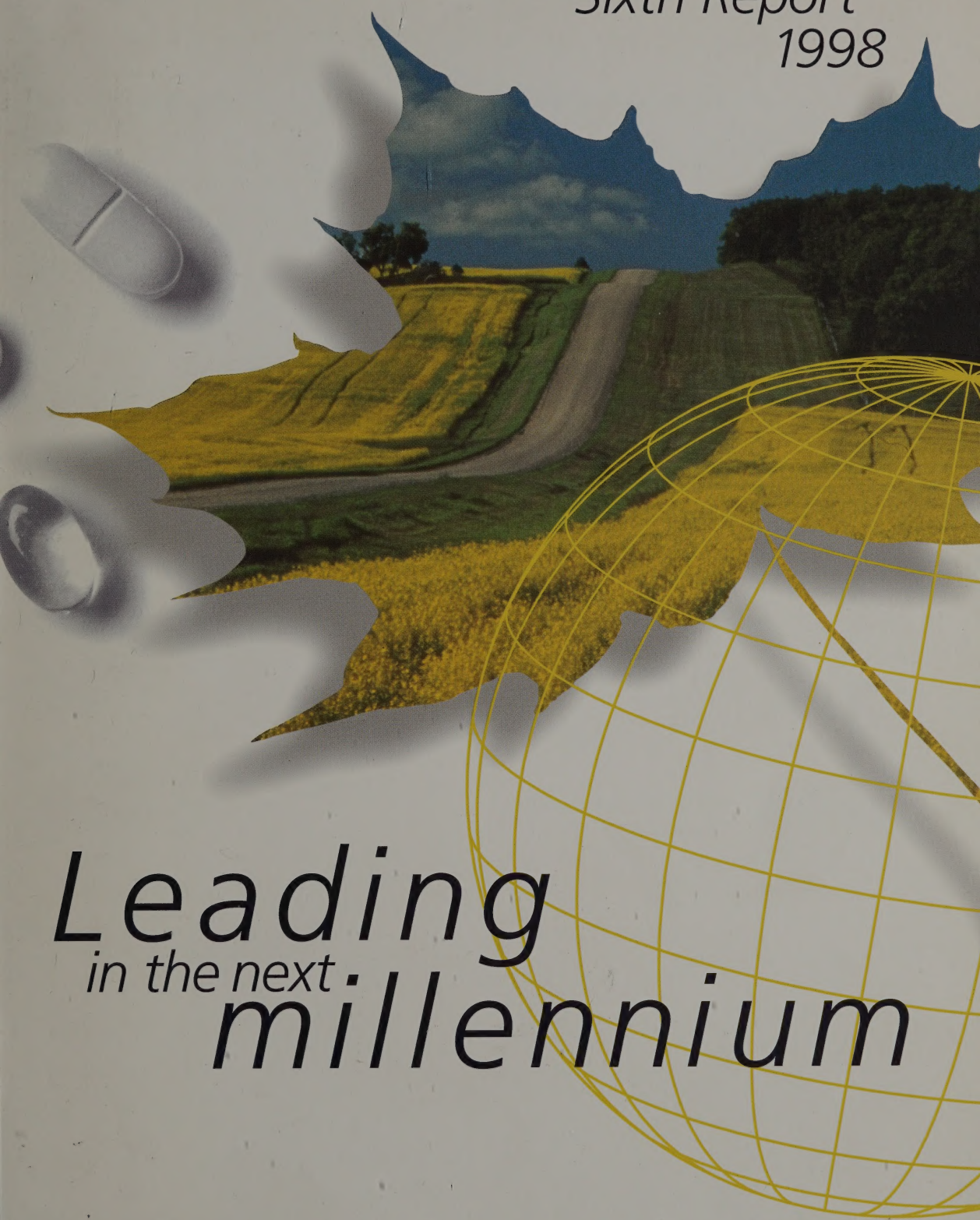
National Biotechnology Advisory Committee

Sixth Report
1998



Leading in the next millennium

Canada

National Biotechnology Advisory Committee

Sixth Report
1998

Leading in the next millennium

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February 16, 1998

The Honourable John Manley, M.P.
Minister of Industry
11th Floor, East Tower, 235 Queen Street
Ottawa, Ontario K1A 0H5

Dear Minister Manley:

In submitting this report to you, I believe the National Biotechnology Advisory Committee (NBAC) has met the challenges you put before it in Ottawa last March. The intervening months have been exciting for all of us closely involved in the process. We have learned a great deal from each other's perspectives as academics, CEOs, and finance and legal experts during deliberations on national priorities for this dynamic technology, which holds such promise for future generations of Canadians.

On March 18, 1997, you met with the NBAC to discuss national and international developments in biotechnology and future directions for revitalizing Canada's biotechnology strategy. At this meeting, you compared the Canadian biotechnology industry to the Canadian aerospace and telecommunications sectors, and charged the Committee to submit a report to you by the end of 1997 that would benchmark Canadian biotechnology in the international context.

You requested that the report include recommendations to enhance the competitive position of the Canadian biotechnology industry. You also asked the Committee to give you advice on possible changes to its mandate and composition, recognizing the accelerating pace of the scientific and technological advances underlying biotechnology and its important implications for the economy and society.

The starting point for the Committee's work in the summer and fall of 1997 was the Fifth Report of the NBAC, issued in 1991. Let me note in passing that it was heartening to the members to realize how much progress the Government of Canada has made in implementing the recommendations of the Fifth Report. Indeed, we recognize that the current strength and vitality of the Canadian biotechnology sector is, in many respects, a direct result of government actions to implement the 1991 recommendations.

As Chair of your committee, I thank you for the opportunity to present this report. I respectfully request you to publish and circulate it to those of your Cabinet colleagues whose departments address the various aspects of this pervasive enabling technology. Implementation of the wide range of recommendations tabled in the Sixth Report will require a concerted effort by many federal departments in partnership with the broader stakeholder community.

The NBAC recommends that the report be circulated to Standing Committees of the House, particularly the Industry and Finance Committees, as well as to parliamentarians.

The Canadian public, whose lives today are being enriched through the application of biotechnology in the health, agriculture and environment sectors, may also be interested in reacting to the report and its findings. The NBAC recommends, in this regard, that you circulate the report broadly through Industry Canada's *Strategis* Web site so that it can reach a national and international audience.

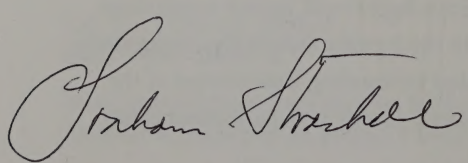
From the outset, we have been aware of the Canadian Biotechnology Strategy (CBS) renewal exercise currently underway in government. NBAC lead authors met with leaders of the CBS Task Force working groups to exchange information and invite their ideas on issues for our consideration. We anticipate that you and your Cabinet colleagues will be responding to the NBAC Sixth Report in the context of the CBS revitalization. NBAC is ready to play an active role in the CBS renewal process as the range of issues is deliberated. We are also prepared to participate in regional and sectoral public consultations.

Your committee members are prepared to meet with members of other federal science and technology advisory bodies, such as the Advisory Council on Science and Technology, and the Forest Sector Advisory Council, to facilitate coordination. Finally, recognizing that it will take some one to two years before the new CBS is fully implemented, your present committee looks forward to continuing to provide advice to the Government to ensure the development of a sound future strategy for Canadian biotechnology.

Members of the NBAC look forward to meeting with you to discuss the NBAC Sixth Report. We are eager to participate in a launch of the Sixth Report that will make its findings widely known to all stakeholders who have an important role to play in strengthening the biotechnology sector in Canada. In 1991, the NBAC Fifth Report was launched in a high profile press conference in Toronto with subsequent regional releases. In 1991 the NBAC members also met with key Cabinet ministers and through a concerted action plan actively disseminated the report's recommendations nationally. In 1998, we look forward to a central launch of the Sixth Report and would be pleased to meet with ministers who share responsibility for biotechnology and their deputies. In addition, we look forward to releasing and promoting the report's recommendations in our respective regions of Canada.

In conclusion, the Committee wishes to thank you for the opportunity to respond to your challenge and to produce this review of Canadian biotechnology. We hope the NBAC Sixth Report will provide you with valuable input to revitalize Canada's Biotechnology Strategy, leading into the next millennium.

Yours sincerely,



Graham Strachan, Chair, NBAC

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Executive Summary

In March, 1997, the Hon. John Manley, Minister of Industry for Canada, asked his National Biotechnology Advisory Committee (NBAC) for a report card on biotechnology. In his request, the Minister underlined two requirements for the report: 1) an international comparison that would show Canada's competitive position relative to biotechnology in other countries, and 2) reflection on the structure of NBAC itself and the role of an essentially industry-based committee in providing advice to government.

This report, the sixth prepared by NBAC, is the result. It represents the combined efforts of 19 dedicated women and men, some of whom are engaged in basic scientific research, some in building the biotechnology industry, and yet others whose interests are in facilitating public understanding of and participation in technology issues. The members volunteered hundreds of hours of professional time during the past 10 months to ensure that the Minister received the best possible advice.

Each chapter went through more than a dozen drafts before the committee members were satisfied that they had explained the issues adequately. More than 100 national and international experts were consulted. In addition, a "Youth Team" of graduate student researchers worked in the summer to develop background information for NBAC's lead authors.

This report contains some 40 recommendations designed to pinpoint the specific changes members believe government should act on if Canada is to grow as a global leader in this field. Of these, NBAC places top priority on three: **political championship of biotechnology in Canada, the availability of highly qualified human resources, and competitive policies on intellectual property protection and regulatory approvals.** These three priorities must be accompanied by measures to improve access to capital, by a significantly reinforced science and technology base and by a national conversation, led by a renewed advisory body, that addresses socio-ethical issues and facilitates public awareness and input into policy.

Taken together, the recommendations in the NBAC Sixth Report constitute steps in a single coherent strategy to position Canada as the number three global player in sales of products of biotechnology by the year 2005. More specifically, if the steps outlined in this report are adopted, NBAC believes the Canadian biotechnology industry can increase current revenues by a factor of five (from $1.1 billion to $5 billion) and the number of biotechnology jobs threefold (from 11,000 to 30,000) in the same time frame if the business and investment climate in Canada at least matches that of our key competitors.

This strategy covers, in particular, pharmaceutical products and agricultural products, the largest and most vigorous biotechnology sectors in Canada.

The strategy has five major elements, each of which is supported by recommendations:

1) the affirmation of the importance of biotechnology to Canada's preparations for the next millennium

Biotechnology is revolutionary in its sweep. It promises more effective treatments for life-threatening diseases and conditions, such as cancer, AIDS, osteoporosis and asthma, that are among the most burdensome ailments to sufferers and health care systems alike.

Biotechnology also promises more abundant and beneficial food and more high-value-added crops for exporters such as Canada. Biotechnology can deliver more environmentally friendly manufacturing and farming technologies, help the commercial fishery restore itself on both coasts, build a more competitive forestry sector and provide productive answers to toxic waste problems through bioremediation.

None of this is science fiction. Biotechnology is here, now, in stores, in food, and hospitals. Reaffirmation of biotechnology as a national priority would demonstrate that Canada's government leaders are on top of the changes and working to help Canada achieve its potential as a leader in this field.

2) the commercialization of the discoveries and products now in the pipeline, so that Canada can achieve its commercialization objective of $5 billion in sales

Canada's biotechnology companies are growing. Over one hundred beneficial products are currently in the pipeline. Achieving $5 billion in sales would bring Canada to 10 per cent of the world market share from its current 5 per cent. To do this, we need to at least double current revenue every four years between now and 2005.

To accomplish such a revenue surge, Canadian companies must 1) overcome the current constraints on accessing the global pool of people who excel in the challenges of commercializing biotechnology, 2) ensure a steady flow of funds to move down the product development cycle, thereby capturing more value for Canada and 3) overcome the tax constraints on participating in international strategic alliances for product development and commercialization. In addition, our business schools and community colleges must build stronger programs to train managers in strategic alliance management and build awareness of international regulation of biotechnology companies.

"Let government and the private sector work together constructively in partnership to successfully commercialize biotechnology in Canada."

Graham Strachan

3) the reinforcement of Canada's science and technology base, especially in genomic sciences, so that Canadians can continue to develop the science that underpins product development

Achieving Canada's competitive goal will require 1) federal government reinvestment in the budgets of federal granting councils to triple the 1993–94 budget by 2003, 2) a major effort to speed up and strengthen technology transfer between academia and industry, 3) obtaining access to the global pool of talent that has proven its excellence in these capacities and 4) a stronger effort to bring more of Canada's brightest young people into biotechnology.

4) strengthening Canada's intellectual property protection laws to bring them into full conformity with global (i.e. World Trade Organization) standards, and making the operations and decisions of Canada's excellent regulatory system clearer and more transparent

This element of the Report urges that full conformity with Canada's key competitors and global standards in intellectual property is strategic to the country's success. It also recommends deepening public awareness and confidence in what is an admirable, science-based risk assessment system that has evolved over a century of dealing with new products and new crops.

5) undertaking a national project to engage all Canadians in a dialogue about biotechnology

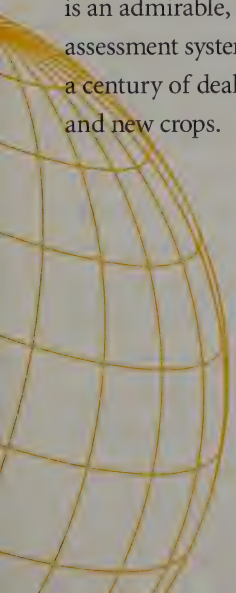
As with other technologies, many biotechnology applications carry some risks alongside their benefits. Some also raise important socio-ethical issues that need to be debated and considered in decision making. It is imperative that we attend to the need for increased public awareness and confidence. To this end, we have suggested some substantial modifications to NBAC so that it can contribute to the development of ongoing conversations in a variety of fora.

Conclusion

Taken together, these five themes constitute a strategy for achieving exponential growth in Canadian biotechnology, and each of the five reinforces the others. Each element is essential to the ability of Canadian biotechnology companies to out-compete their international rivals and capture more value for Canada. Each element is essential if Canada is to be a platform for industry expansion.

The recommendations are designed to be read in the context of the arguments and analyses presented in this report. A complete list of recommendations, with references to the sections of the report where they occur, can be found in Appendix 1.

The targets are ambitious but attainable if the Government of Canada adopts the public policy changes recommended in this report. The costs of leadership will be far outweighed by the benefits to Canada.



Poised for Leadership

CHAPTER 1

ABSTRACT This report is a wake-up call. Canada can be a leader in the next millennium in biotechnology – one of the most important and exciting new technologies. However, seizing that opportunity will pose some public policy challenges. If those challenges are not met, then Canada's vast potential in biotechnology will remain largely unfulfilled.

1.0 A Wake-up Call for the New Millennium

Biotechnology has taken off in Canada. It has progressed from a research focus to one that now includes commercialization, the emphasis on innovation, manufacturing, marketing and selling. Products of biotechnology are increasingly entering the national and international marketplaces, and are transforming almost every aspect of life. This trend is already under way, and will last well into the next century.

Biotechnology and its applications will rival information technology as a "change maker" in terms of economic growth, employment and quality of life. Beyond noticeable breakthroughs in health care and productivity for farms, forestry and aquaculture lie future organic computers and memories – even nano-technology and self-organizing construction and manufacturing systems – now only the stuff of science fiction. Biotechnology is as important for the new economy and environment of the next millennium as the internal combustion engine and electricity were for agriculture, transport, and aluminum, pulp and paper and industrial production at the start of this century. The inevitable conclusion is set out in the following:

The extent to which Canada adopts biotechnology and pursues its development and application will significantly determine the country's future economic status and its role in world affairs.

1.1 Who Benefits?

As with other revolutionary technologies, biotechnology will transform almost all aspects of life, but who will benefit? Canadians will in terms of quality of life, health care, environmental sustainability and economic growth.

Biotechnology opens up new strategies for combatting disease. Today's biomedical research, yielding effective new treatments and diagnostic tools for cancer, atherosclerosis, osteoporosis, asthma and AIDS, is anchored in biotechnology. Biotechnology used in bioremediation can tackle environmental contamination — from cleaning up

oil spills to removing valuable minerals from mine tailings. This enabling technology provides the key to sustainable forestry and aquaculture.

The use of biotechnology will help meet the food needs of a burgeoning world population that will double from its current level by the year 2050. Domestically and globally, society benefits from higher yielding crops that feature improved storage characteristics and require fewer pesticides and fertilizers.

With biotechnology, Canada can remain at the leading edge of agricultural practice and dramatically enhance the value of its agricultural exports. Without biotechnology as a powerful ally there may not be enough food in the future, and the use of traditional chemical techniques will fail to combat pests effectively, while creating extensive environmental hazards.

Without biotechnology, humans may well stand unarmed against diseases once thought vanquished by antibiotics but that are now proving resistant to conventional treatments. Without biotechnology, society will be less able to deal with the public health consequences of globalization, as diseases once confined to specific regions of the world move freely around the planet, attacking whole populations that lack the immunities developed in the originating regions.

The biotechnology revolution can help achieve significant new levels of health-care productivity. Demand for biopharmaceuticals will also be accelerated by the changing nature of health care. The advanced countries of the Organization for Economic Co-operation and Development can only maintain their health programs in the face of a rapidly aging work force if health care becomes more cost-effective. Performance-sensitive health-care management systems are constantly searching for the most effective therapies. Biotechnology can provide them.

Safer, more effective drugs, and higher yielding new crops that reduce environmental stress are only part of the biotechnology future. Biotechnology also offers the promise of helping renew and reinvigorate Canada's forests and fish stocks. Environmental applications can provide more cost-effective ways of cleaning up pollution and enhancing toxic chemical degradation.

Biotechnology can also allow for efficient, environmentally friendly manufacturing using photosynthesis. Canadian researchers have demonstrated the production of industrial chemicals, fine chemicals and even pharmaceuticals using genetically modified plants. All this and more is either already here or emerging over the horizon as Canadians' knowledge and ability to work with genes steadily grows and improves.

The revolutionary impact of biotechnology will be felt in other ways as well. Already, Canadians have witnessed the overturning of two high-profile wrongful murder convictions through the use of DNA testing. But along with the benefits of genetic screening go concerns about privacy protection. Along with our growing ability to alter the earth's genetic stock of plants and animals, go concerns about biodiversity. Like all revolutions, biotechnology creates its own context that imposes adjustments on society.

Part of the challenge posed by biotechnology is managing the process of change in accordance with Canadian values of fairness and tolerance. But meet that challenge we must!

1.2 Roadmap to the Report

In March 1997, the Hon. John Manley, Minister of Industry, called on the National Biotechnology Advisory Committee (NBAC) to provide him with a considered view of the state of the biotechnology sector in Canada

and of the public policy requirements to help build industry competitiveness. This report also represents a key input to assist the Minister in the renewal of the Canadian Biotechnology Strategy (CBS).

The report shows that Canada is making significant strides in developing robust, export-oriented biopharmaceutical and bio-agricultural industries. The successful commercialization of Canadian biopharmaceutical products will add dramatically to Canada's productivity and help it maintain its position as one of the world's wealthiest economies, as well as strengthening its leadership in bio-agricultural applications.

Yet, for Canada to capture the full value of its potential in these industries, changes must be made in some aspects of public policy. The following chapters discuss those changes and the rationale for them:
Chapter 2 examines the challenge of commercialization and underlines the urgent need for entrepreneurial managers and access to capital; among the identified solutions are options on tax policy and immigration rules.

Chapter 3 calls for rebuilding our formerly world-class science and technology base and urges improvement in its funding and technology transfer capabilities.

Chapter 4 examines Canada's intellectual property (IP) policies and procedures for regulating health, safety and the environment. The chapter concludes that the regulatory framework remains sound, but suggests important changes to enhance the speed of service and to bring Canada's IP in line with that of World Trade Organization (WTO) partners, while increasing the transparency and public awareness of the Canadian regulatory system.

Chapter 5 reviews the socio-ethical dimension of biotechnology. It scans international best practices for assessing socio-ethical issues, facilitating public input and analysis, and fostering public awareness and public confidence. To that end, Chapter 5 also makes the case for the evolution of NBAC from its current format as a primarily industry-based advisory group to a more broadly representative advisory body.

Chapter 6 explores in more detail the mandate, membership, reporting structure and public role for a broadened advisory body to government, and NBAC's relationship to a renewed Canadian Biotechnology Strategy.

1.3 The Next Wave

What is behind the biotechnology surge? The developments in biotechnology are similar to those in information technology in the previous wave. Moore's Law, first stated in 1965, predicted microprocessor power would double every 18 to 24 months until the end of the century. Since 1965, the number of actions a chip can perform in a second has increased from 10,000 to 100 million, driving information processing costs straight down and opening the door to thousands of software developers. Their activities, in turn, have added momentum to further hardware development.

In biotechnology, three main science and technology drivers are generating capabilities and opportunities of the same order of magnitude:

- **our exponentially growing understanding of human, as well as plant and animal genomes:** Scientists now expect to complete the cataloguing of the entire 100,000-gene human genetic code by the year 2004, with our knowledge of genetic function increasing just as quickly. That

knowledge is steadily being transformed into more effective treatments of genetic diseases, cancers and some infectious diseases. Similar understanding of plant and animal genomics allows researchers to develop higher yielding crops and to improve livestock herds.

- **the ability to make products of biotechnology more economically:** It used to take large stainless steel fermenters to produce useful quantities of therapeutic and diagnostic proteins. Now, with new biological techniques, the same yields can be obtained using advanced and considerably smaller fermenters. Soon commercial-scale production will be possible in transgenic animals and plants, harnessing genes *in situ* to produce pharmaceutical and diagnostic products.

- **the use of advanced informatics to produce better drugs more rapidly:** This capability allows the development of large diverse libraries of novel drug candidates and the electronic screening of thousands of these per day for potential efficacy.

1.4 Canada's Biotechnology Advantages

Canadian companies are becoming successful innovators because biotechnology is a made-to-order technology for Canada. Historically, Canada has had a strong network of excellent universities, an extensive agricultural and natural resource base, internationally acclaimed medical schools and teaching hospitals, and citizens who expected high-quality health care. Canadian scientists have earned global distinction, and participate fully in biotechnology networks that touch virtually every research centre on the planet. Canadian companies, also, are active in a dynamic web of strategic alliances that span every major market in the world.

Every region of Canada shares in the success of biotechnology. British Columbia is strong in biopharmaceuticals and forestry research and development (R&D); Saskatchewan is a recognized global leader in agricultural R&D and applications; Ontario and Quebec are leaders in biopharmaceuticals and food processing, with Quebec ahead in commercialization. Atlantic Canada, too, has excellent biotechnology research centres for aquaculture, forestry and biodiversity.

These cross-country capabilities and biotechnology networks are a significant reminder that Canada is a place where women and men of varied social, linguistic and cultural backgrounds can work together to achieve a strong, united, social and economic future for our nation. As the table below shows, every region has attracted investment into biotechnology companies.

Biotechnology Financing by Region

	West	Ontario	Quebec	East	Other	Total
1991–1995						
C$million	421	412	268	8	6	1,115
%	38.0	37.0	24.0	0.7	0.5	100
No. of placements	61	54	49	3	3	169
1996						
C$million	312	196	505	2	3	1,018
%	30.6	19.0	50.0	0.2	0.3	100
No. of placements	24	19	23	1	2	69

Source: National Research Council

Genome Studies in Canada

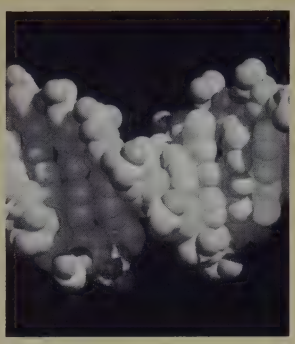


Photo: National Research Council

The Canadian Genome Analysis and Technology Program (CGAT) is part of an international effort known as the Human Genome Project, a 15-year, $3-billion scientific undertaking to develop a detailed map of the complete nucleotide sequence of the genome of humans and many other biologically important organisms (e.g. bacteria, yeast, nematode and fruitfly).

Almost entirely sponsored by governments in North America, Europe and Japan, **the Human Genome Project is by far the largest project ever undertaken in biological research. It will produce the basic information necessary to guide and shape society well into the 21st century**. The impact of this program will be felt in health care, agriculture, aquaculture, forestry and industrial biotechnology. In the agricultural sphere, for example, Japan has a large rice genome project, and the US Department of Agriculture invests in excess of $58 million annually in the Plant Genome Research Program, which is aimed at identifying the complete genomic sequences of important agricultural plants.

Initially, Canada committed $22 million over five years to CGAT. Canada, a minor but active participant in the international cooperative effort ($462 million worldwide from government sources), has recently virtually eliminated its support. The CGAT was funded initially by federal and voluntary sector agencies, Industry Canada, the Medical Research Council (MRC) and the National Cancer Institute of Canada. It supported pioneering studies in the human genome, as well as those of yeast and other organisms. In addition to the science component of genomic research, CGAT also undertook significant research into the Medical, Ethical, Legal and Social Implications (MELSI) related to the understanding and utilization of genomic information. Canada had developed an international reputation in MELSI issues in genetic research. In this domain, Canada's **Social Sciences and Humanities Research Council (SSHRC)** took outstanding leadership. However, this funding was terminated in 1997, leaving only a meagre $1-million commitment from MRC to support peer-reviewed genome research that falls under MRC's mandate.

Genome studies are only the beginning of a whole new generation of technologies that will define the leading edge of biotechnology research for the next decade. The extensions of genomics are already here: functional genomics, the global compilation of genetic functions; bioinformatics, the acquisition, organization, analysis and dissemination of the mountain of new genetic information; proteomics, the study of protein-protein interaction and the composition of protein complexes; domain studies, the analysis of global protein structure from the viewpoint of the basic protein building blocks; and differential gene expression, using very sophisticated DNA-array "chip" technology. Major recent efforts in the United States and elsewhere have already gone beyond the application to the human organism of genomics and its more recent extensions, and are now beginning to focus on maize, rice, wheat and other important food crops. **The intellectual property flowing from these studies will drive biotechnology competitiveness in the next decade**.

The reduction in Canada's genome program has not only hollowed out the country's existing capability, but has jeopardized the chances of Canada leading the next wave of postgenomic studies. Canadians have major international strengths in areas that give them the potential to become world leaders. Yet, owing to a lack of resources, Canada stands to lose out on the commercialization of agricultural, medical, silvicultural and aquacultural discoveries in the 21st century. ■

1.5 Potential Threats

Canada has built well on the early international leadership and momentum it established in biotechnology through outstanding scientific research. But unless changes are made and new policies adopted, Canada's time as a major player in the field could end. Already, Canadians firms are beginning to lose ground to relative newcomers in the race to successful commercialization. There is a need to increase the breadth and scope of financing and enterpreneurial management, as well as address significant gaps in public policy. Particularly alarming, for example, is the country's emerging weakness in genomics development, an area in which, as researchers, Canadians were strong a decade ago.

The elimination of a formal genome program has not only had a significant negative impact on Canada's current ability to participate in genome research, but has jeopardized Canadian chances of being involved in, let alone leading, the next wave of postgenomic innovation. Consequently, Canada stands to lose its leadership role in agricultural, medical, silvicultural and aquacultural discoveries in the 21st century.

1.6 Sustaining Momentum: Public Policy Guidelines

As Canada's focus on biotechnology shifts from R&D to commercialization, a number of changes to public policy are in order if commercialization is to take place successfully in Canada. In the chapters that follow, NBAC examines the need for change and makes specific recommendations in areas ranging from tax policy to the structure of the bodies that give advice to government. Beyond specific recommendations, there are some general policy guidelines whose spirit should infuse public policy in this emerging source of national competitive advantage. Considerations for public policy can be summarized by the following statements:

Biotechnology is big, both as an economic driver in the next millennium and as an enhancer of Canadians' quality of life. Biotechnology has momentum as a transforming new industry. Don't stop it. Although some in Canada might like to try, other countries will continue in their biotechnology efforts. The economic and other penalties of not taking a leadership role will be very large. Don't legislate; regulate through more easily adjustable guidelines. With the speed of development, any legislation would soon be out of date. Foster public debate. Industry needs to move forward with consumer input and support. Stay flexible. Canada must keep its policies flexible enough to keep pace with the biotechnology revolution, through effective and timely regulation, active public debate and consultation, and maintenance of its strong science base.

1.7 Benchmarks and Targets for Biotechnology in Canada (1997–2005)

Until the last few years, biotechnology companies had been predominantly North American. In the early 1990s, Canada had as many biotechnology companies as Japan and as many as the whole of Europe. This has abruptly changed. There is fast-growing competition from Europe, Latin America,

and the Pacific Rim, backed by large national resources. In terms of the numbers of biotechnology companies, Canada is now third behind the United States and Europe.[1] In another study for the Department of Foreign Affairs and International Trade in 1997, Canada placed fourth in a list of countries with a business climate that encouraged the development of biotechnology, behind the United States, the United Kingdom and Australia.[2]

Nevertheless, Canada remains a significant player with an ability to dramatically improve its standing. Ernst and Young's 1997 biotechnology industry review showed that, when compared to the United States and Europe, Canada's biotechnology industry led in year-over-year growth in sales, revenue, R&D and new market capitalization. Despite this growth, there is no room for complacency because, as the table on industry performance below shows, Canada is now behind in such key indicators as revenue per employee, the ratio of R&D to revenue and R&D per employee when compared to international competitors.

As the figures in the table below show, Canadian companies must become more competitive in their operations. Clearly, the data imply that revenue per employee must rise about 70 per cent to match the most dynamic competitors. As well, R&D as a percentage of revenue must climb another 15 per cent to reach 50 per cent, and R&D per employee must increase almost threefold to match U.S. levels. These are ambitious targets. To achieve them, the Canadian industry will have to double its revenues every four years up to the end of 2005, the target year.

At the same time, the number of people employed in biotechnology in Canada will have to rise from 11,000 to nearly 30,000. That is, the base of highly qualified personnel and the experienced cadre necessary for this industry to meet its full potential will have to triple over the next eight years. To support these developments, it will also be important to increase funding to Canada's science and technology base to the average level of its G-7 partners (i.e. as a percentage of Gross Domestic Product, Gross Domestic Expenditures on Research and Development would increase from 1.6 to 2.5).

Core Biotechnology Industry Performance: Canada, the United States and Europe (1995 fiscal year)

	Canada	United States	Europe
Companies	224	1,287	584
Total revenue (C$million)	1,141	20,440	2,124
R&D expense (C$million)	403	11,060	1,110
Employees	11,000	118,000	17,200
Revenue per employee (C$)	104,000	173,000	123,000
R&D as a % of revenue	35%	54%	52%
R&D per employee (C$)	36,600	93,700	64,500

Source: *European Biotech '97: A New Economy*, the Fourth Annual Ernst and Young Report on the European Biotechnology Industry, April 1997, p. 2; *Canadian Biotech '97: Coming of Age*; Ernst and Young Fourth Report on the Canadian Biotechnology Industry, 1997, Table 1.

1 *Canadian Biotech '97: Coming of Age*, Ernst and Young Fourth Report on the Canadian Biotechnology Industry, 1997.

2 *A Comparative Overview of National Biotechnology Strategies*, prepared by Ernst and Young for the Department of Foreign Affairs and International Trade, April 1997.

1.8
A Call for Leadership

The NBAC Sixth Report argues that building global competitiveness in the biotechnology industry depends on a number of interrelated factors. Top among them are the political championship of biotechnology, the availability of highly qualified human resources and competitive policies on intellectual property protection and regulatory approvals.

These priorities must be supported by enhanced access to capital and underpinned by a strengthened science base. Of additional importance to a thriving industry are public awareness and input and broad public considerations of the socio-ethical dimensions of biotechnology. Finally this report argues for a national conversation about biotechnology led by a modified advisory body with a public role.

Currently, the Canadian biotechnology industry has approximately five per cent of the world's market for products of biotechnology and more than 100 promising products in the pipeline. The NBAC believes that by the year 2005 the Canadian biotechnology industry has the potential to reach $5 billion or 10 per cent of world biotechnology product sales, which are forecast to reach $50 billion by 2005.

This industry goal is challenging but compelling. To achieve it, Canada needs clear leadership to focus national attention on biotechnology, an area in which Canada has so much potential and so much to offer the world. Canadians have the capacity to achieve this, but it is urgent that the country's public policies be consistent, supportive and effective. If not, Canada will be surpassed by other nations more determined and energetic than us to achieve biotechnology leadership. Canada must wake up... and catch the wave!

Recommendation

The National Biotechnology Advisory Committee (NBAC) recommends that the Minister of Industry champion biotechnology, recognizing that the extent to which Canada adopts biotechnology and pursues its application and development will significantly determine the country's future economic status and its role in world affairs.

As a national goal, Canada should adopt a target of capturing 10 per cent ($5 billion) of global sales by the year 2005 of products of biotechnology (forecast to reach $50 billion annually by 2005). In achieving this goal, industry should match its top competitors in the ratios of R&D to revenue and revenue per employee.

While continuing to lead in biopharmaceuticals and agricultural biotechnology, Canada should strengthen significantly its focus on applying biotechnology throughout the resource sectors including forestry, fisheries and energy, as well as mining and the environment.

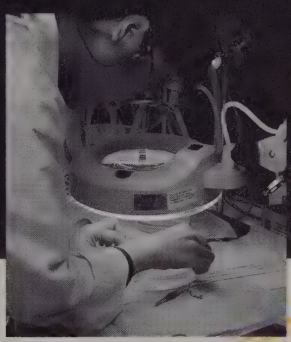


Photo: Allelix Biopharmaceuticals Inc.

NBAC places top priority on political championship of biotechnology, availability of highly qualified human resources, and highly competitive policies on intellectual property protection and regulatory approvals. These priorities must be accompanied by measures to improve access to capital, a significantly reinforced science and technology base, public awareness and input into policy and consideration of a socio-ethical framework facilitated through a national conversation about biotechnology led by a renewed advisory body.

Commercialization: Capturing Value in Canada

CHAPTER 2

ABSTRACT Canada's biotechnology industry is undergoing a strategic shift from research to commercialization. This new emphasis requires changes in public policy if Canada is to benefit fully from the extraordinary opportunity offered by its biotechnology capabilities. The recommendations that follow are listed in order of urgency: access to top scientific and management talent, measures to improve the flow of capital to the industry, and changes needed to make Canada an attractive hub for international biotechnology partnerships. Two specific sectoral applications of biotechnology are also examined: agriculture and forestry.

2.0 Building on Success

During the early 1980s, Canada identified biotechnology as an important strategic technology. **The National Biotechnology Strategy (NBS), composed of supporting policies and key investments, was initiated in 1983.** The focus of the Strategy was the creation of a world-class research infrastructure from which to launch a competitive Canadian biotechnology industry.

The National Research Council (NRC), through the Industrial Research Assistance Program (IRAP), supported links between basic and applied research and an emerging Canadian bio-industry. Parallel programs, such as the Networks of Centres of Excellence (NCE), developed a number of powerful R&D networks among leading biotechnology research groups.

The payback is that, in 1997, Canada has a thriving bio-industry that has raised billions of dollars on capital markets, and created over 11,000 direct high-value jobs in the core biotechnology industry. Currently, there are over 100 innovative products in the commercialization pipeline.

Now, Canada's biotechnology industry, which historically has focussed on research, faces a strategic shift from a research orientation to commercialization. The prospects for commercialization are enormous. It is estimated that the total market for biotechnology applications will reach $50 billion annually worldwide in the next eight years.[1]

Canada should target 10 per cent of that total $50 billion world market by 2005. It is within our grasp!

However, to earn that share Canada needs to create and implement a more aggressive value-capture strategy. Otherwise, Canadians risk missing out on global market

1 *Sector Competitiveness Frameworks.* Bio-Industries: Part I Overview and Prospects, Bio-Industries Branch, Industry Sector, Industry Canada, March 1997.

More Canadian Value-added Generates Higher Returns to Canada

Development Stage	Estimated Returns or Royalties (%)	Worldwide Sales (C$million)		
		100	500	1,000
Research	2–5	2	10	20
Phase I Clinical Trials	5–10	5	25	50
Phase II Clinical Trials	10–15	10	50	100
Phase III Clinical Trials	15–25	15	75	150
Manufacture	35 +	35	175	350

Source: NBAC estimates

opportunities and the jobs, sustainable economic growth and quality of life improvements that leadership in biotechnology can bring.

The remainder of this chapter outlines the public policy steps relating to commercialization that have to be taken if this target is to be realized.

2.1 Maximizing Value-added in Canada

Previous NBAC reports have called for measures to underpin the creation of a Canadian biotechnology industry. The successful development of the industry to this point reflects the implementation of many of those recommendations. **Now, as the industry moves to its next phase of development, it is imperative to broaden the discussion from one that emphasizes precommercial issues to a wider discussion of the appropriate value-capture strategies for the country as a whole.**

In this context, what is the best approach for maximizing value-added in biotechnology in Canada? NBAC believes that commercial success must be measured by the amount and value of Canadian activity. Canadians have invested in basic research resulting in the creation of intellectual property. As with Canada's forests and minerals, intellectual property is a valuable resource.

Just as Canada's export mix is evolving from primary commodities to include high-value-added products, the same should happen with biotechnology. Canada should produce the furniture rather than just selling the lumber. The commercialization component of a renewed Canadian Biotechnology Strategy should focus on helping Canadian companies achieve the following objectives:

- **creating additional value by taking products further into the development cycle**
- **establishing many more cGMP facilities in Canada** [2]
- **establishing greater international marketing and sales presence.**

Recognizing and addressing these key objectives is paramount if Canada truly is to reap the full social and economic benefits of the biotechnology revolution. For example, an integral component of commercialization is the development of alliances with large multinationals. More specifically most biotechnology companies commercialize their products by licensing intellectual property, manufacturing and marketing rights. The closer the product or drug is to market when the licensing arrangements are made, the greater the royalties accrued to Canada on sales and potential profits. The increase can be dramatic.

As the table above shows, a company that sells its product or technology at the earliest stage, preclinically in the case of a pharmaceutical drug, generally receives

2 cGMP stands for certified Good Manufacturing Practices, an internationally recognized quality standard.

modest royalties from its partner of between two and five per cent of sales worldwide. If the drug is taken through Phase I clinical trials and shown to be safe for certain indications, the company will likely receive between 5 and 10 per cent of worldwide sales. For a company that completes all three clinical trial phases and receives marketing approval, the royalty on worldwide sales will likely jump to 25 per cent or more; with manufacturing rights, the company can increase its return to over 35 per cent.

Canada's value-capture strategy should, therefore, aim to help industry improve its ability to realize this higher degree of success by making it easier for companies to move further into the product development cycle.

2.2 Fundamental Requirements for Success

To build this enhanced product development capability, Canada's biotechnology industry has several fundamental requirements. All elements are essential. Yet one can rank these priorities according to their urgency.

At the present time, the most urgent need to be met to ensure successful commercialization is access to experienced management and scientific personnel. Closely following is the continued access to capital and global distribution channels often only strategic partnerships can bring.

Other critical requirements are discussed in subsequent chapters. One of these needs is continued access to innovative research, hitherto an area of Canadian strength but one that is now eroding, as discussed in Chapter 3. Industry also needs a well-defined regulatory environment and informed domestic consumers that accept the industry's products. In large measure these are advantages that Canada already enjoys. Nevertheless, they cannot be taken for granted; chapters 4, 5 and 6 address ways of strengthening these advantages.

The focus of this chapter is on commercialization and ways in which government and industry can cooperate to ensure that Canada positions itself as a leader in this new and exciting technology. The recommendations that follow are generic and designed to address the most pressing issues across areas of biopharmaceuticals, agricultural biotechnology, aquaculture, mining, environmental biotechnology and forestry. Following these cross-sectoral discussions some sector-specific recommendations are added.

2.3 Access to Highly Qualified People (HQP)

Experienced Managers

Successful senior managers and the expertise in product commercialization that are required to develop a dynamic biotechnology company to maturity are in short supply. Even the slow-growth scenarios in the government's forecasting models show that 10,000 new management and technology jobs will be created in biotechnology before the year 2000.[3] The industry's growth rate in 1996 was nearly 20 per cent,[4] a rate difficult to sustain without drastic action to improve access to qualified employees worldwide. Our target is 20,000 new jobs by the year 2005, based on the full potential of Canada's biotechnology industry.

3 Human Resources Development Canada, *Building Long-term Capability Now: Canadian Human Resources Study in Biotechnology*, May, 1996.

4 Ernst and Young, *Canadian Biotech '97: Coming of Age.*

Training: The Long-term Solution

Canada has a serious lack of programs to nurture the management skills, such as product development, strategic alliance management, international regulation and technology transfer, required by Canada's strong core of established R&D-driven companies. Over the medium to longer term, industry and government need to work with universities and business schools to establish programs so industry executives can develop such talents.

Recommendation

NBAC recommends that industry, business schools and community colleges work together with the Biotechnology Human Resources Council to design executive development programs, master of business administration courses and certificate programs on managing international biotechnology companies. Specialized material should initially cover international trade, investment and alliance strategies, as well as international regulatory affairs in the areas of agriculture and pharmaceuticals.

Adjusted Immigration Rules: The Near-term Necessity

In the short term, the immigration rules that hinder the recruitment of highly qualified offshore experts for openings in Canada need to be eased. Otherwise, Canadian investment will, itself, move offshore to the experts. Additionally, Canada needs to launch a worldwide recruitment drive to bring this talent to the country. Recruiting skilled people is paramount to ensuring the success of a national value-capture strategy.

Recommendation

NBAC recommends that the federal government ease immigration rules that hinder timely recruitment of highly qualified individuals and launch a recruitment drive for highly qualified biotechnology managers, provide work permits to spouses of qualified recruits and work with the Biotechnology Human Resources Council to address urgent human resource issues.

This is not a new issue. These and similar recommendations have been repeated for several years, starting with the *Science and Technology Task Force Report on Immigration* in 1990 and the NBAC report in 1991. Since then the Industry-Government Steering Committee on Immigration Issues has been established within Human Resources Development Canada (HRDC). Supported by HRDC, the Biotechnology Human Resources Council (BHRC) has been established to address human resource issues, including strategic immigration. The need is growing increasingly urgent. NBAC strongly urges action now.

Another Key: Salary and Income Tax Harmonization

Canada's personal income tax rates are clearly out-of-line with those of its major trading partners. As a consequence, it is difficult to attract and retain highly qualified achievers, despite other quality-of-life attributes that Canada offers. In the absence of a significant cut in upper-end marginal tax rates, some Canadian jurisdictions have developed recruitment strategies. For example, Quebec has a two-year tax holiday for knowledge workers. Another approach would be to permit a special tax-advantaged savings plan, locked up in the company for a period of years, to provide an incentive by

Recommendation

NBAC recommends that, in the absence of bringing Canada's marginal income tax rates into line with those of its competitors, the federal government adjust the tax rules to permit companies to provide offsetting tax breaks, such as a two-year tax-advantaged savings plan, for newly recruited and highly qualified scientists and managers to encourage them to come to Canada.

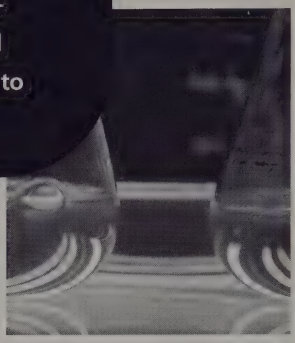


Photo: National Research Council

equalizing the tax rate for the individual with that of their country of origin. This tax credit would also facilitate technology transfer and skills diffusion to a permanent Canadian work force.

2.4 Improving Access to Capital and the Flow of Funds

The Canadian biotechnology industry is composed primarily of small, early-stage companies involved in a rapidly growing, capital intensive industry. So great is their progress that, in 1996, Canadian biotechnology companies raised more than C$1 billion in capital — equivalent to all the capital raised in the sector in the previous five years[5] — almost all of it in biopharmaceuticals.

This record performance must continue unabated if commercialization is to proceed. Just to satisfy the capital requirements of the Canadian biopharmaceutical industry for commercializing products now under development will require investments totalling between C$1 billion to C$1.5 billion each year — without additional R&D and without any new products being added into the pipeline.

Where is the development money to come from? To a large degree, biotechnology industry growth in Canada is almost totally dependent on capital markets. With the right incentives and suitable economic conditions, the potential exists for capital markets to continue to meet the needs of the industry. Nevertheless, a decline in public equity investment (as occurred between 1992 and 1995) would dramatically slow the rate of development of Canadian companies and their products.

More important however, given the current reliance on capital markets in conjunction with the actual operating impact of certain government tax-related programs, is that the resultant balance of forces seems to encourage companies to sell intellectual property early, and let large, established companies do the development. Yet, as NBAC has already indicated above, the key to a strong national value-capture strategy for Canada is to ensure that Canadian companies can move as far down the product development path as possible.

This report cannot provide exhaustive analysis in support of any one recommendation or set of recommendations. This is especially true for recommendations on taxation. Nevertheless, **any new national strategy for biotechnology must address the tax program impact on the flow of funds to biotechnology companies. For it seems to us, based on our experience in the commercialization of products of biotechnology, that the tax system has a negative effect on the industry's growth in Canada.** Consider, for example, the effect of some anomalies of the R&D tax credit, as applied to biotechnology.

5 Cameron Groom, First Marathon Securities.

2.4.1 R&D Tax Credit Issues

One of Canada's most successful business programs, the R&D tax credit program allows companies to earn tax credits for performing R&D in Canada. The effect of this is to reduce the cost of R&D to the company in recognition of the broader benefits to society that flow from having such R&D performed.

The success of the R&D tax credit program can be seen in the leading position Canada has achieved in such knowledge-intensive sectors as telecommunications and aerospace, to name but two. A key component of Canada's overall industrial development strategy, the R&D tax credit has had significant positive impact on the creation and support of the biotechnology sector. At the same time, however, some of its administrative rules seem to be operating at cross purposes to the general thrust of the program.

Access to Ongoing R&D Tax Credits for Precommercial Public Companies

Public biotechnology companies that are precommercial are penalized under the R&D tax credit system in comparison with private companies. The regulations currently in place hinder commercialization because the public company loses access to essential cash. **The 35 per cent refundable tax credit private companies receive reverts to a 20 per cent non-refundable tax credit for a public company.**

Since biotechnology companies are not generally profitable when they issue their initial public offering, or in the following years, the current tax credit system is of little real value to them.

Access to Accrued R&D Tax Credits

NBAC would also like to see the R&D tax credit program modified to allow earlier access to accumulated credits in recognition of circumstances specific to biotechnology.

Unlike the other sectors in which this program has been applied, biotechnology companies are still generally small, early-stage companies, yet they must sustain development cycles of 7 to 10 years before a product comes to market. They can do this by raising money on capital markets and, as discussed above, by accumulating tax credits on their books until they become profitable.

This means that money earned by those companies when they perform research is unavailable until the end of the product development cycle. The biotechnology industry accounts for $500 million or 10 per cent of all unutilized tax credits.

Currently the average accrued tax credit for biotechnology companies is twice that of non-biotechnology companies claiming the credit.[7]

Recommendation

NBAC recommends that the federal government adjust its tax rules to allow emerging[6] public companies to keep the same level of refundable tax credits as private corporations for a period of five years after their initial public offering.

6 "Emerging" refers to early-stage, precommercial companies that are not yet profitable.

7 Industry Canada internal study.

To understand the impact of this, it is important to realize that the product development cycle for biotechnology is approximately twice as long as the development cycle in other industries. The extra length of the cycle puts enormous pressure on biotechnology companies to find sources of cash to fund product development until they generate sales. As a result, too many companies are obliged to make licensing arrangements too early in the product development cycle, and the returns to Canada are significantly below potential.

Moreover, the accumulation of tax credits on a company's books also makes such a firm an attractive takeover target for more profitable companies that are able to set the credits against hefty earnings.

This is especially true when biotechnology stocks enter a period of volatility. Often, a high price-to-earnings ratio is a company's major takeover defence. When the ratio drops, perhaps owing to a market shock, then these companies become exceptionally vulnerable. In fact, it is sometimes possible to acquire their technology for the price of the bricks and mortar, which, when the tax credit is taken into account, amounts to a gift.

While takeovers by foreign multinational enterprises can lead to economic benefit for Canada, more often than not they result in a leakage of technology from the country, and only infrequently to commercialization in Canada.

Allowing earlier access to the earned tax credits for specific and legitimate commercialization applications would help correct this situation. Instead of allowing firms to accumulate unused tax credits through the long product-development cycle, the government should consider the accrued R&D tax credit as a potential cash reserve for companies that need financing to move their products through the final stages of commercialization.

Allowing these credits to be accessed for specific commercialization activities, such as building a manufacturing facility and initial marketing, or setting up an international sales force, would help provide additional financing that companies often need to take their products further into the development cycle, thus supporting more national value-capture.

Not every company would wish to take advantage of this procedure. But for those with substantial accumulated tax credits, the ability to make early use of them provides a way to move ahead especially if external shocks make capital markets skittish for a time.

In addition, allowing the accrued tax credits to flow to a partnership (as opposed to an acquisition) would facilitate alliances and allow Canadian firms to retain, as well as exploit, the intellectual property already paid for, in part, by Canadian taxpayers. Activity stimulated by such tax credit access (and by the accelerated and increased sales of the successfully commercialized products) would rapidly repay the outlay. In particular, this measure could encourage a partnership to locate in Canada.

It should be noted that if the government adopted the recommendation to make all R&D tax credits refundable, then the problem of accessing accrued credits would no longer continue to grow. Rather, it would become an historical anomaly to be resolved over time.

What would it cost to change the R&D tax credit program in this way? In all probability, there would be net gains rather than costs to the federal (and provincial) tax authorities if the program was adjusted as recommended in this report. The accelerated outflow of tax credits would be applied to specific commercialization purposes that would generate taxable activities sooner (and therefore be of higher net present

value). There would also be additional taxable revenue from having Canadian companies performing value-added and job-creation activities in Canada that, in all probability, would be undertaken by a strategic alliance partner outside Canada under present circumstances.

In fact, the outflows involved on the tax credit side are relatively small for biotechnology: some $500 million in total, or roughly $18 million per company in unclaimed tax credits.[8] The latter is also roughly the cost of building a cGMP-dedicated manufacturing facility. In keeping with the national value-capture strategy, the funds could be used to enable Canadian companies to move further along in product development by building enhanced manufacturing competencies when appropriate or by strengthening their international roles and marketing presence.

Recommendation

NBAC recommends that the federal government modify the R&D Tax Credit Program to allow public companies with accrued R&D tax credits to use those credits for specific commercialization activities, such as dedicated licensed manufacturing facilities or approved partnerships.

2.4.2 Strategic Partnering and the Tax System

An equally critical factor in the financing of biotechnology companies is strategic partnerships with multinational pharmaceutical companies. These links are essential channels that provide Canadians with much-needed access to markets, capital and highly qualified people. Partnering offers Canadian biotechnology companies the most effective avenue to successful commercialization. If Canada really wants to be a major player in this industry, it must adjust its tax system.

As the table on collaborative agreements shows (see next page), Canadian biopharmaceutical firms have been especially active in making strategic links with major North American and international partners. A recent survey reports[9] that the average Canadian biopharmaceutical company has 8.2 alliances. Large companies average 14 alliances, and medium to small and very small enterprises average between 5 and 11 alliances each. Nearly two thirds of these alliances are with companies in the United States, Europe and Japan, Canada's major trading partners.

International strategic partnering is of vital importance to the commercialization of Canadian biotechnology products. International alliances encourage Canadian companies to proceed with product development on a global basis and bring concomitantly higher returns to Canada.

It is dismaying to realize that the Canadian tax system discourages international alliances in which the Canadian partner contributes intellectual property.

Immediately, when the partnership is formed, the intellectual property becomes taxable at a deemed fair value. This happens even though no cash has been received and there remains considerable development work to be done before the product is ready to go to market. This discourages partnerships that share Canadian IP with international firms, which often control channels to lucrative global markets. Canadian companies prematurely entering into licensing arrangements with foreign partners results in lower rates of return to Canada.

8 Industry Canada analysis of the top 34 publicly traded biotechnology companies in Canada.

9 *Canadian Biotech '97: Coming of Age*, Ernst and Young Fourth Report on the Canadian Biotechnology Industry, 1997.

Collaborative Agreements of Canadian Biotechnology Firms

Biotechnology Company	Partner	Product	Use
Aeterna Laboratories	Estee Lauder	Cosmetic Ingredient	Cosmetics
Allelix Biopharmaceuticals	Astra AB	ALX1-11	Osteoporosis
Allelix Biopharmaceuticals	Eli Lilly	EAA Receptors	Obesity
Allelix Biopharmaceuticals	Groupe Fournier	Lipids	Atherosclerosis
Allelix Biopharmaceuticals	Hoechst-Roussel	D4 Dopamine	Schizophrenia
Axcan Pharma	Schwartz Pharma	URSO Ursodial	Lysis of Stones
BioChem Pharma	Astra AB	Analgesics	Pain Relief
BioChem Pharma	Glaxo-Wellcome	3TC/Lamivudine	AIDS
Biocoll	Depuy	Dynagraft	Dermatology
Biomira	Chiron Corp.	Theratope	Cancer Vaccine
Cangene	NABI	WhinRho SD	Hemolytic Disease
Cangene	Octapharma AG (Europe)	WhinRho SD	Immune Thrombo-cytopenic Purpura
Hemosol	Fresenius	Hemolink	Blood Substitute
ID Biomedical	Pasteur Merieux Connaught	Tuberculosis Vaccine	Tuberculosis Vaccine
INEX Pharmaceuticals	Chiron Corp.	Factor VIII	Blood Clotting
Microbix	Gensia Scicor	Generic Urokinase	Dissolve Thrombi
QLT Phototherapeutics	Beaufour IPSEN	Photofrin (Europe)	Cancer Therapies
QLT Phototherapeutics	CIBA Vision Ophthalmics	Photofrin	Maculer Degeneration
QLT Phototherapeutics	Sanofi Winthrop	Photofrin	Cancer Therapies
StressGen Biotechnologies	Genzyme/CMDF	Stress Gene Therapies	Cancer Therapies
Synsorb	Takeda Chemicals	Synsorb Pk	Gastrointestinal
Theratechnologies	Beaufour IPSEN	TH 9507 GRF Analog	Wound Healing
Visible Genetics	Amersham	Reagents and Marketing	Reagents

Source: First Marathon Securities

This is just one specific example of a general situation. The problem is that the Canadian tax system, in effect, discourages types of international partnering in whose success the Canadian government would retain an interest. On the face of it, this amounts to a decision to restrict the Canadian tax base to entities within the geographical boundaries of Canada, an approach that seems seriously at odds with today's commercial realities.

It perhaps needs to be stressed that NBAC is not arguing for permission to move partially tax-funded products offshore to escape taxation. Rather, NBAC is suggesting the opposite. We support allowing Canadians to create additional value offshore if that is what is required, and we support allowing Canadian tax authorities to participate in the success of that product. Adjusting the tax rules in this way would increase Canadian product development with higher gains for Canada.

Canada's tax system discourages strategic alliances from developing technology

licensed from third parties in Canada. The system gives Canadian biotechnology companies an incentive, when purchasing a new technology from a third party, to have an entity other than the Canadian company make the purchase to facilitate partnering with that technology at a later date. This displaces from Canada activity that might otherwise occur here.

Recommendation

NBAC recommends that the federal government commission a review of Canadian tax policy as it relates to intellectual property and "know-how" in the formation of international strategic alliances and joint ventures. The goal of the study would be to determine how revisions to the tax system could provide Canada with competitive advantage in the critical area of strategic partnering.

The rules would be easiest to change for partnerships in which Canada could retain the ability to tax the Canadian partner on its share of the partnership income. Naturally, some anti-avoidance provisions would be required to prevent abuses. Another useful change would be to allow the transfer of technology in exchange for shares of a foreign corporation. This would require more extensive changes to the rules for taxation of foreign affiliates.

The aim of this strategy would be to allow companies to defer the tax on the initial transfer, when the company is not yet making income from the technology, but then to be taxed on subsequent dividends. This would be akin to licensing technology in exchange for a future royalty.

In all probability, there are many instances in which Canada's general inability to retain an interest in global alliances based on the development of intellectual property has the effect of discouraging such alliances. Certainly, Canadians need to understand in much greater depth the ways in which the tax system discourages the realization of Canada's full potential as a platform for major alliances.

2.4.3 Other Tax-related Issues

Capital Cost Allowance

The Capital Cost Allowance (CCA) is a potent tool for promoting commercialization. For example, the Ontario government introduced a 100 per cent same-year tax write-off of the costs involved in acquiring intellectual property and technology. The current federal CCA schedules are unrealistically long and inappropriate for competition in today's global, knowledge-based economy.

Why Accelerate Capital Cost Allowance?

The rationale for capital cost depreciation schedules is that the cost of new equipment should be depreciated over the useful life of the equipment in order to show the true state of affairs in an operating company. The problem with the depreciation tables as applied by the federal government is that the rate of depreciation is too slow for today's dynamically innovative economy. Companies are obliged to depreciate equipment well beyond its useful life especially in dynamic areas such as intellectual property and new technology.

Recommendation

NBAC recommends that the federal government review its tax treatment of capital costs with a view to making available the same write-off provisions as exist in Ontario.

This has harmful effects. Company tax returns understate the true operating costs of the company, thus opening it to what is, in effect, a tax on its capital as well as its profits. Companies are not encouraged to purchase new technology. This inhibits the uptake of new advances. The total effect of delayed depreciation is to weaken the competitiveness of Canadian companies in comparison with others.

Allowing companies to claim their capital costs for intellectual property and advanced technology in the year the expenses occurred would strengthen competitiveness.

It would allow Canadian companies to deepen their capital resources and take up new technology as quickly as it became available, in effect raising their productivity and competitiveness. Governments would enjoy a net gain from a change in these rules as applied to biotechnology companies because such companies would become profitable more rapidly and stay that way longer. Their capacity to innovate would no longer be hobbled by this rule.

Staying Tax-competitive with the United States

The 1997 reduction of the U.S. capital gains tax to 20 per cent will give a further stimulus to investment in the United States and put Canada at an even greater disadvantage by comparison. If Canadians are serious about competing in a global, knowledge-based economy, the government must ensure that the tax system enhances the competitiveness of Canada's economy in comparison with that of the U.S., and that Canadian capital markets remain no less attractive than theirs. Otherwise, biotechnology in Canada will be unable to expand to meet the goals set out in this report.

2.4.4 Other Recommendations to Improve the Flow of Funds

Canada-wide Securities Regulations

As a consequence of provincial jurisdiction in securities matters, public offerings and regulatory compliance are more complicated in Canada than in other countries. In order to tap Canada's capital markets as easily as those of the U.S. and the rest of the world, it must become as easy to launch a public offering anywhere in Canada as it is in the U.S. This requires that a single, standardized procedure be put in place at the national level. This could be achieved through a common securities regulator at the federal level or by mutual recognition of approved documentation such that documents acceptable in one jurisdiction would be acceptable to the other.

Recommendation

NBAC recommends that the federal government support (either through mutual recognition or by setting up a National Securities Commission) the creation of a country-wide set of standards for public offerings and company reporting requirements.

Labour-sponsored Venture Capital Funds

The creation of Labour-sponsored Venture Capital (LSVC) Funds by federal and provincial governments has had an outstandingly positive effect on the establishment of entrepreneurial biotechnology initiatives. The availability of this capital spawned an exciting array of health-care and biopharmaceutical ventures. For the first time, there is ample capital available for medically related ventures.

However, the LSVC organizations still fall short of their full potential owing to an inability under current rules to serve provincial interests while maintaining an international focus. Other shortcomings include a lack of funds for agriculture- and natural-resource-based applications of biotechnology and a lack of seed capital for early-stage financing.

Recommendation

NBAC recommends that the federal government work with the provinces to modify investment restrictions and encourage Labour-sponsored Venture Capital Funds to function as competitive venture capitalists by allowing them greater room to participate in financing emerging companies both nationally and internationally.

Government should consider allowing Labour-sponsored Venture Capital Funds, which currently are limited in the amount of money they can put towards public (versus private) companies, to invest a small proportion of their capital in early-stage public biotechnology companies.

The federal government should work with the provinces to review respective mandates to achieve a more global perspective by reducing current restrictions that inhibit national and international participation. This would stimulate more public-offering activity in Canada and allow Canadians to participate in biotechnology successes nationally. LSVC funds should also be allowed and encouraged to allocate a portion of their funds to foreign international syndications. This would facilitate the development of relationships with influential international venture partners, thus broadening access of Canadian ventures to global financial resources. As well, the increased international experience will enable LSVC funds to offer broader advice and expertise to help their client firms internationalize.

Government should encourage the establishment of sector-specific Labour-sponsored Venture Capital Funds (i.e. forestry, ag-bio, and environment funds). Government should also facilitate the availability of specialized seed-capital pools to encourage development of precommercial opportunities.

Technology Partnerships Canada (TPC) and the Industrial Research Assistance Program (IRAP)

The Technology Partnerships Canada (TPC) repayable investment program was established to support near-market development projects in the aerospace and defence sectors and in environmental and enabling technologies, including biotechnology. It was expected to play a strong role in fostering growth in the biotechnology industry. Currently, however, biotechnology applications to this program far exceed its capacity to fund them. The current allocation to the sector can only support two to three major projects over the life of the program. The funds available under TPC for biotechnology should be expanded so that it can fund at least 10 major projects a year, given the growth in this industry sector.

Recommendation

NBAC recommends that the funds available for biotechnology under Technology Partnerships Canada be expanded so that it can fund at least 10 major projects a year. The project ceiling capacity of the Industrial Research Assistance Program should be expanded to enable the Program to play a larger role in seed-capital financing of R&D.

IRAP has played an important role in helping biotechnology companies move from the laboratory bench to the venture capital financing stage. Nevertheless, under current rules, IRAP is limited to $350,000 in funding for individual projects. There remains a gap in available funding for projects at the seed-capital level of between $500,000 and $1.5 million. IRAP's funding capacity should, therefore, be expanded to help close this gap at the seed-capital level.

2.5 Agricultural Biotechnology: A Growing Opportunity

In the early 1990s, promising first-generation agricultural biotechnology companies in Canada that had proprietary technology in transgenic crop breeding were absorbed by larger multinational companies with the financing and vision to take new products through long development phases into successful commercialization.

In the next few years, products from the second generation of agricultural biotechnology companies will be ready for commercialization. As with the bio-pharmaceutical sector, Canadian agricultural companies need to take their products further into the development cycle, building their commercialization base in Canada and developing real Canadian company participation in international marketing and sales activities before they can reap maximum financial benefit.

As with pharmaceuticals, the opportunities are huge. The projected global market for transgenic crops by the year 2000 is estimated at $2-$3 billion, growing to $6 billion by 2005.[10]

Already, transgenic cotton, soybeans and corn are grown by American farmers, who are reaping the benefits of reduced chemical input costs and increased yields of from 5 to 10 per cent. As an example, *Bacillus thuringiensis* (Bt) corn[11] is giving farmers additional revenue of US$20-$75 per acre depending on the severity of the insect infestation.

In the United States, seed companies are also realizing substantial benefits from premium prices that farmers are prepared to pay for a superior product. Seed premiums may vary from US$50-$70 per bag.

In three years these transgenic seeds have already captured 20-50 per cent of the U.S. acreage of these traditional crops and are forecast to stabilize at levels of between 80-95 per cent by the year 2000.[12]

Present-day seed companies have either grown from successful agricultural chemical companies or have developed strong business alliances with them. These arrangements are important for the seed companies because they are able to build on well-established farming distribution networks and product marketing strategies.

Those transgenic crops most advanced in commercialization in Canada are canola, corn and potatoes, with flax seed and

Recommendation

NBAC recommends that its proposals for improving access to qualified managers and scientists, improving the availability of seed capital and enhancing the role of Labour-sponsored Venture Capital Funds, as well as for granting early access to earned R&D tax credits, also apply to agriculture biotechnology.

10 Agriculture Canada.

11 Corn genetically engineered to be resistant to insect attack by expressing a Bt gene, eliminating the need for a pesticide.

12 *NatWest* Report, 1997.

soybeans poised to become the fourth and fifth. In just two years the acreage sown to transgenic canola has gone from 0 to 1.6 million hectares (30 per cent of the total sown area) and is estimated to reach 2.6 million hectares in 1998.

Corn and potatoes, just a year behind canola, have already reached approximately 121,400 and 2,800 hectares, respectively.[13] These acreage figures are likely to expand rapidly.

Encouragement of these trends, with sound economic framework policies and coordinated regulatory frameworks between different levels of government, will enable Canadian farmers to reap tremendous benefits and to remain competitive with U.S. farmers. Superior yields for the farmers also mean financial benefits to the seed companies.

In Canada, the intellectual property for transgenic seeds approved for use belongs to several widely owned multinational companies, mostly headquartered outside Canada.

These companies recognize Canada's strategic advantages in agriculture and are making substantial investments in developing new crop varieties here.

Public policy needs to be developed to assist second-generation biotechnology companies now beginning to emerge around new technologies coming off the laboratory benches.

Ag-bio Product Convergence

Encouraged by the success of transgenic modification of conventional crops, research in Canadian universities, government laboratories and industry has already shown that valuable pharmaceuticals, fine chemicals and altered oils can be produced by the genetic modification of various oilseed crops. The production of a variety of different chemicals and pharmaceuticals has already been demonstrated in field trials in Canada, raising the prospect that valuable pharmaceuticals could be efficiently synthesized by transgenic plants grown under highly segregated, tightly controlled conditions.

Much of this new development work is being pioneered by university and government scientists and the more than 70 Canadian-owned smaller firms developing agricultural applications of biotechnology.

These companies encounter the normal problems faced by small, high technology start-up and developing companies, which are compounded by the relative invisibility of the agriculture sector to venture capital partnerships. Not only do these small

Biotechnology Financing by Sectors Using Capital Investments

	Human Health	Agriculture/ Food	Aquaculture Bioremediation	Total
1991–1995				
C$million	1,034	60	21	1,115
% of total $million	93	5	2	100
Number of placements	151	13	5	169
1996				
C$million	1,007	11	-	1,018
% of total $million	99	1	-	100
Number of placements	68	1	-	69

Source: National Research Council, January 9, 1998

13 Agriculture Canada.

companies need long-term capital, they also need urgent access to internationally experienced biotechnology managers and timely advice on export markets, regulatory issues and intellectual property protection.

Biotechnology Financing by Sectors Using Capital Investments

Capital investment placement activity in health-care-related biotechnology exceeds that in food and agriculture by a margin of 10:1 from 1991–1995. Ag-bio placements worsened significantly in 1996 to almost 1 in 70. The table on the previous page compares placement activity by biotechnology sector between 1991 and 1995 with that in 1996.

Needed: Innovative Public Policy

Continuing public policy development is required to meet the changing needs of technology developers in agricultural biotechnology. Innovative approaches to nurturing small, ground-breaking biotechnology companies through the start-up phases have been developed in Saskatchewan and Quebec and are now being applied in other provinces. The key to the success of the Saskatchewan initiative has been the use of a not-for-profit catalytic organization to initiate and support biotechnology using early-stage investment programs, business relationship brokering, industry education programs and public communication. Also crucial to success has been the fostering of industry clusters (see boxes on Saskatchewan and Quebec, pages 27 and 28).

Essential to these developments has been the commitment of federal and provincial politicians and public officials at the highest levels to ensure that the right conditions, such as essential infrastructure, financial support and the presence of experienced highly qualified scientists and technical support personnel, were in place to support companies seeking locations that support innovation.

It is important to recognize the significance of this cluster approach if Canada is to realize fully the huge future economic potential of the application of biotechnology to agriculture. Enabling small companies to grow into internationally successful entities by developing and marketing their own intellectual property is the surest way to bring the full financial benefits of Canadian R&D to the Canadian economy.

Recommendation

NBAC recommends that, recognizing that the success of Ag-West Biotech Inc. and the successful clusters of innovative industries in Quebec are the fruits of close cooperation among federal, provincial and municipal governments, industry and the finance and research communities, this cooperation be adopted across the country as an essential element of a strategy to ensure Canada maximizes its potential in this technology.

"In the new millennium, biotechnology will be at least as important for the economic growth of Canada, as electricity, metallurgy, chemistry and forestry were at the start of this century."

Michel Chrétien

"Accelerating advances in agricultural biotechnology must be Canada's national mission for the next decade. Driven by national champions and commensurate investments, we will consolidate our global competitive position in agriculture to reap the social and commercial rewards."

John Cross

Promoting Ag-bio in Saskatchewan — Innovation Place

In 1989, recognizing both the challenges and the potential of agricultural biotechnology, the Saskatchewan provincial government and the University of Saskatchewan supported the formation of Ag-West Biotech Inc., a non-profit corporation, to act as a catalyst for agricultural biotechnology initiatives. **Successfully securing federal and provincial involvement, Saskatchewan is now home to 40 per cent of Canada's agricultural biotechnology industry and supports one of the world's top agricultural research centres, which features more than 400 public sector and 300 private sector research scientists spending more than $80 million annually on research.**

Agencies and institutes supporting biotechnology research in Saskatoon include Agriculture and Agri-Food Canada Research Stations, NRC's Plant Biotechnology Institute, the Saskatchewan Research Council, the University of Saskatchewan, including the Veterinary Infectious Disease Organization, and the Protein, Oil and Starch Pilot Plant.

Saskatchewan's agricultural biotechnology cluster has pioneered cell fusion and tissue culture techniques for agricultural applications. The researchers are world leaders in crop microbials (biopesticides and biofertilizers) and transgenic wheat, and have a number of world firsts to their credit, including genetically engineered flax and genetically engineered animal vaccines.

The province's Innovation Place is one of North America's most successful research and development parks, whose 30 ag-bio tenants include some of the largest agricultural companies in the world. On the grounds of the University of Saskatchewan, the research park provides vital infrastructure to create a technology link among industry, academia and government laboratories through mechanisms such as the L.F. Kristjanson Biotechnology Complex (a custom-designed greenhouse and laboratory space for transgenic plant research) and the Atrium Fermentation Support Facility.

Many of today's new biotechnology companies had their genesis in university laboratories. To aid in the successful transfer of technology and expertise and to translate it into commercial success, the University of Saskatchewan has established modified co-op and training programs in addition to its technology transfer program.

Investment and business development are supported by Ag-West Biotech Inc. and the Saskatchewan Opportunities Corporation, as well as through access to a well-informed and vibrant regional pool of venture capital. **The Saskatchewan government continues to champion agricultural biotechnology through long-term commitments to tax incentives, education, training and financing**.

The end result is a vertically integrated ag-bio research community that features efficient and coordinated research along the entire value chain, going beyond selling to become the purveyor of value-added, identity-preserved products — from DNA to the dinner plate. ■

Photo: National Research Council

Promoting Biotechnology Clusters in Quebec

Biotechnology became a top priority for economic development in Quebec during the 1980s, reflecting a collective willingness to protect intellectual property and to use to the maximum the advantages of the proprietary positions of Quebec's discoveries.

The provincial and municipal governments, particularly in Montreal, Quebec and Sherbrooke, collaborated with chambers of commerce, the corporate services sector and industry. The provincial government developed a series of measures to help these emerging industries. A 40-per-cent tax credit was allocated for expenditures related to researchers' salaries and university research contracts. A 20-per-cent tax credit was given for the salaries of in-house researchers, and a two-year personal income tax exemption was allowed for salaries of recruited foreign researchers.

The government encouraged innovative products through its public expenditures in health care and other sectors of the economy. It created a favourable environment for industry clusters including biotechnology. For example, "Pharma-vision" became the vehicle for clusters including companies, research centres and universities. Together, they created synergistic advantages in human resources, expert personnel, general infrastructure and capital availability.

"Techno-vision" groups were created and venture capital companies were developed. Some such as Innovatech-Montreal ($300 million), Innovatech-Quebec City ($60 million) and Innovatech-Sherbrooke ($40 million) received direct government subsidies. The Fonds de Solidarité du Quebec and the Caisse de Dépot et de Placement du Quebec founded subsidiaries directly related to new technologies. Biocapital was created and is now in its third financing phase. Sofinov is a major player in developing new start-up companies in collaboration with academic scientists. Recently Sofinov joined with the Canada Development Corporation to form T2C2, a new company whose role is to help scientists in academic settings prepare business plans and develop novel technologies for immediate transfer to emerging companies.

For the past 10 to 15 years, successive ministers of Industry, Commerce, Science and Technology followed the same type of policies, thus developing a momentum to face the challenges of the new millennium. The value-added product industries will have priority and act as flagships in many regions of the province, while Montreal will remain the locomotive powering the biotechnology, transport and communication sectors, as identified by its chamber of commerce in the mid 1980s. ■

"Numerous examples demonstrate Canada's leadership in environmental protection using biotechnology applications. Encouraged by our numerous successful showcases, the environmental biotechnology industry needs increased governmental support to grow on the international level."

Jean Shoiry

The table below shows an approximate picture of sales of Canadian biotechnology firms involved in the forest sector.

Canadian Biotechnology Firms Involved in the Forest Sector

Products/ Services for the Forest Sector	Biotech R&D (C$millions)	Biotech Revenue (C$millions)
Biofertilizers	1.9	2.2
Biopesticides	12.3	37.6
Pulp and paper	18.2	66.9
Bioremediation	1.0	31.0
Tree improvement	8.9	8.4
TOTAL	42.3	146.1

Source: *Canadian Biotechnology 1997 Directory*, using all-inclusive figures for each company.

2.6 Forest Sector: Challenges and Opportunities

Canada's forest sector is the most important industrial engine in the country. It is, consistently, the single highest contributor to Canada's positive balance of trade (C$33 billion in 1996), outpacing all other manufacturing sectors combined. Close to one million Canadians depend on this sector for their livelihood.

Internationally, the demand for wood products and fibre is constantly increasing, with the United Nations' Food and Agriculture Organization (FAO) estimating that world demand will increase by 50 per cent by 2010 and double by the year 2020 from present levels. At the same time, Canada's share of the global market, traditionally the largest and currently about 19 per cent, is decreasing. In the face of stiff competition from the Nordic countries, the United States, New Zealand and Australia, and emerging competition from the former Soviet Union and South American countries, some of the answers for the future lie in productivity improvements in managed forests and in preserving our pristine old-growth forests. Biotechnology can provide some solutions by increasing the hardiness of trees in commercial plantation, accelerating their growth cycle, and protecting them from pests and disease using environmentally sound products and strategies.

Canada is a world leader in applied and basic research in forest biotechnology. However, only a few products and processes of biotechnology have been commercialized.

These include forest protection using *Bacillus thuringiensis* and insect virus biopesticides; forest regeneration; enzyme treatment of wood pulp, reducing the need for chemicals that produce dioxins; and also pulp and paper mill effluent treatment.

Biotechnology can keep Canada's forestry sector competitive. Yet this is unlikely to happen without more commercially sustainable natural resource management practices. The adoption of biotechnology by the forest industry requires the commitment of provinces. This is because, in most cases, it is the provinces, not the companies, who own the forests and the land.

Reforestation and forest management is the responsibility of the provinces. Forest product companies negotiate harvesting quotas and land leasing arrangements with the provinces. Provinces are not driven by

Recommendation

NBAC recommends that the federal and provincial governments work with the forestry industry to develop an improved incentive structure (e.g. long-term land-leasing contracts and cutting rights) that would encourage it to invest in biotechnology applications.

commercial considerations to innovate. This acts as a strong disincentive to forest companies to commit to long-term research, and innovation in Canadian managed forests is slow to occur.

This is despite the fact that genetically engineered trees with higher yields are under commercial cultivation in the United States. The uptake of genetically modified trees by Canadian forest companies could dramatically improve the competitiveness of the forestry sector but only if provinces introduce necessary change.

The goal posts are being moved as fast as Canada's trading partners can innovate. The United States and Europe already have locked up considerable intellectual property in herbicide- and insecticide-resistant conifers and poplars.

Despite Canada's having the world-class Forestry Research Institute in New Brunswick, Canadians are only now beginning to put that capability to work in developing commercializable products and processes. In terms of commercial applications of forest biotechnology, Canada lags behind the United States and New Zealand. Other countries with strong research capabilities include France, Australia and Sweden. In addition, there is emerging competition from Latin American countries such as Chile, Brazil and Argentina that

Bio-Energy: Contributing Solutions to the Global Climate Change Challenge

Bio-energy has arrived in Canada and already has an important role to play in the evolution of new "green technologies." Bioenergy can diminish greenhouse gases. Canadian biotechnology companies have responded to the challenge that greenhouse gases pose to the environment as main sources of pollution and deterioration of the ozone layer.

Companies are positioning themselves to produce clean, renewable alternatives such as biomass-based ethanol and bioremediation technologies.

Photo: National Research Council

"Green Gas": Biomass-based ethanol

Petro-Canada and the Ottawa biotechnology company **Iogen** have signed a landmark deal to produce a pollution-free motor fuel from converted agricultural and wood wastes.

This technology uses bio-engineered enzymes to convert low-cost cellulose into ethanol. Compared with fossil fuels, "green gas" cuts greenhouse gases by more than 90 per cent. The "green gas" technology will give Petro-Canada and Iogen a commanding market-share lead in the race to replace fossil fuels in Canada's transportation sector. ■

multinational forestry companies consider to be development sites for biotechnology applications.

Canada's forests are vital for the future. Not only are they important economic engines, but Canada's 10 per cent share of the world's forests contributes significantly to the lowering of greenhouse gases through atmospheric carbon fixation.

The acceleration of seedling-to-harvest cycles would not only enhance our industrial competitiveness, but would also assist Canada in reaching its international obligations for atmospheric emissions of greenhouse gases. These are two reasons why biotechnology is being highlighted in the S&T module of the National Forest Strategy renewal. There is an urgent need to develop mechanisms to encourage private industry involvement and investment in research and technology applications derived from biotechnology. Federal and provincial governments, as owners of 94 per cent of Canada's forest tracts, should develop new forest resource management policies that would promote the use of the products of forest biotechnology, facilitate the development of research cooperatives and support private investment. This is a long-standing issue that was raised in the 1991 NBAC report.

"Biotechnology has emerged as one of the most promising and crucial technologies for sustainable development in the next century."
Council of the European Commission
***Growth, Competitiveness, Employment – The Challenges and Way Forward into the 21st Century*, 1993.**

"Biotechnology is a powerful development tool for the life science industries, and Canada has the opportunity, through leadership and a positive environment, to be a major player in the future growth of this sector."

Carolyn Armstrong

2.7 Biotechnology and Canada's Other Natural Resource Sectors

This report does not examine successes emerging in the application of biotechnology to environmental remediation, mining or aquaculture. It would be remiss, however, not to underline the opportunity for Canada to capitalize on the power of biotechnology to transform these sectors in the future. Selection of the health and agricultural sectors for focus in this Sixth Report reflects the current competitive edge Canada has gained in these sectors. NBAC urges nevertheless that, although Canada now has a niche in these fields, the government, industry and universities should strengthen Canada's capacity to support the application of biotechnology across the full breadth of its natural resource sector. Benefits could significantly enhance pollution clean-up techniques, reduce toxic acid drainage from mining and dramatically augment depleted fish stocks.

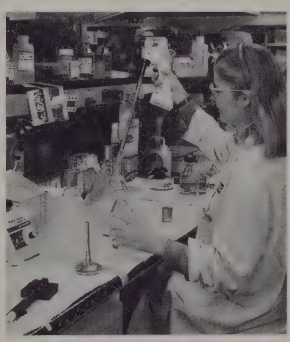


Photo: Allelix Biopharmaceuticals Inc.

Science, Technology and Innovation

CHAPTER 3

ABSTRACT Canada's once world-class biotechnology science base is eroding under cuts in public funding and the outward migration of star researchers. Attracting and retaining the highly qualified people required for a successful biotechnology industry is proving to be a major challenge. To help address this, youth must be encouraged to enter courses leading to a career in biotechnology. In addition, as the House Standing Committee on Finance has recommended for three consecutive years with increasing urgency, Canada's commitment to its federal granting councils must be substantially strengthened. Finally, speeding up the rate of technology transfer from the laboratory bench to the marketplace would increase the rate of return on scarce scientific investments. There are signs this is occurring, but much more needs to be done in universities – and outside – to ensure that a viable Canadian receptor base is in place.

3.0

In a Knowledge-based Economy, Wealth Creation Starts with a Simple Question

Fundamental science is the most powerful driving force for the creation of wealth and jobs in this or any advanced country. The biotechnology portfolio of products now in the first wave of commercialization is based on fundamental discoveries of some 25 years ago. For example, 25 years after monoclonal antibodies (MAbs) were discovered, the first therapeutic MAb was recently commercialized by IDEC Pharmaceuticals.

Photo: Allelix Biopharmaceuticals Inc.

The economic powerhouse of research, the intellectual equivalent of vast deposits of commercially recoverable natural resources, typically starts with a simple question: How does it work? (See the example on page 33.)

As with the other forces of nature, scientific curiosity is inherently uncontrollable. The important thing is to exploit it. The key to cost reduction is not to cut back on research, but to improve the cycle times for bringing potentially valuable discoveries forward from the lab to market, improving technology transfer and shortening the time to payback.

Canada has a rich scientific tradition that spans virtually all fields of scientific endeavour. Based on publication counts, Canada ranks seventh in overall quality of research and third in cost effectiveness of spending in support of basic research, a remarkable achievement in view of the limited research support here compared to our major competitors. In terms of revealed comparative advantage or proportion of scientific papers in a field in the basic scientific disciplines, Canada ranks in the top five worldwide in agriculture, clinical medicine and multidisciplinary research. In molecular genetics, a field that is directly relevant to biotechnology, Canada ranks at the top of the international scale in quality.

Source: Robert M. May. The Scientific Wealth of Nations. *Science* 275 (7 February 1995), pp. 793-4; *Molecular Biology and Canada's Future: Building on Strengths in Canadian Molecular Biology Research*, Final Report and Recommendations, Molecular Biology Committee of the Royal Society of Canada (1994), p. 28.

Low-cost, Long-term Job Creation

In its own right, exploratory or curiosity-driven research has been shown to be one of the lowest cost sources of long-term job creation. Recent figures by the Medical Research Council estimate that 62 high-quality direct and indirect jobs are supported by every $1 million of research funded. Further, estimates show that in the health sector three indirect jobs are created for every new direct employee. The ongoing challenge is to develop and maintain efficient mechanisms to recapture this investment through technology transfer to industry. ■

The Question: "How does a muscle work?"

The Result: Impact on a Billion-dollar Industry

Photo: National Research Council

In 1969, Dr. David MacLennan of the University of Toronto asked a simple question, "How does a muscle work?" His initial work on rabbit muscles led to the discovery, in 1990, of a genetic mutation responsible for triggering a potentially lethal response in 1 in 12,000 children and 1 in 40,000 adults that are given general and local anaesthetics and muscle relaxants.

Interestingly, pigs too can suffer from this genetic mutation. They can, in effect, be scared to death. The stress-induced death of these animals can be triggered when a hog experiences acute stress on the farm or prior to slaughter. This genetic condition also results in poor meat quality.

There are approximately 786 million pigs worldwide[1] with an estimated market value of C$100.8 billion. Approximately 11.8 million of these pigs have the genetic mutation and up to 12 per cent of them will die of stress.[2]

Dr. MacLennan and his co-inventor, Dr. Peter O'Brien, obtained patents for a DNA-based test that can be carried out using a few drops of the pig's blood. As a result of this work, the pork industry can now address these staggering losses through the development of alternative breeding practices. Since the project began, in excess of $2.9 million in worldwide royalties have been generated.

In addition to providing a method to diagnose this condition in pigs, Dr. MacLennan's work has provided valuable insights into the role of proteins in human muscles. His results are as eagerly awaited by basic scientists as they are by agricultural and medical geneticists for practical applications.

All this was initiated by efforts to answer a basic question — "How does a muscle work?" ■

1 In 1996, total number of hogs was 786,635,000. Estimated by the FAS, Dairy, Livestock and Poultry Division (202) 720-1350, VII-20, Table 7- 28.

2 D.C. Seeler, W.N. McDonnel, P.K. Brasur, *Can. J. Comp. Med.* 47.284 (1983).

3.1
The Future of the Science Base

Competition exists worldwide to cut cycle times. In molecular biology, the identification of the application of a gene amounts to defining a product. Increased economic pressures to be first to bring new products to market are fundamentally changing the research process. In today's globally competitive world, diffusion of imported technology is not enough; Canada has to be leading in its creation. Canada cannot lead if its science is derivative. This must be a country poised on the leading-edge. If the application is featured in *Nature*, someone else has already discovered it.

Global pressures to commercialize are today reshaping the research process, traditionally accepted as linear, into an interlocking continuum. Within this continuum, fundamental research can either be conducted as basic exploratory work without a planned application, or as basic directed work to solve questions arising late in the product-development cycle.

"The trend away from curiosity-driven research in favour of highly directed investigation — which is today, toward an incremental approach to innovation that is really sophisticated problem-solving — must not be taken too far. Otherwise, we will deplete the wellspring of truly fundamental innovation on which sustained improvement in the human condition depends."

Peter J. Nicholson, Board Member,
Canada Foundation for Innovation

The biotechnology industry (including large pharmaceutical companies) tends to stress the latter — directed basic research. This is understandable. Industry does not have the capacity to be a major source of support for university-based exploratory or curiosity-based research. Government is the custodian of the national infrastructure to support exploratory research from which the commercial sector can draw fundamentally new ideas for practical applications.

At the curiosity-driven end of the spectrum, where the basic scientific wealth is created for future exploitation, Canada is losing its relative position on the leading edge and is falling to the middle of the pack.

As a percentage of GDP, our GERD, or total investment (industry, universities and government) in R&D, is below the average for G-7 nations.[3] Compounding this trend, federal government investment in R&D is still falling. From 1993 to 1997, the federal government reduced its expenditures on R&D by 9.7 per cent.[4]

Selected International Comparisons, 1995

Country	GERD/GDP (%)
Japan	2.8
United States	2.6
France	2.3
Germany	2.3
United Kingdom	2.0
Canada	1.6
Italy	1.1

Source: *Science and Technology Data – 1997*, Industry Canada, based on OECD Main Science and Technology Indicators, May 1997

3 OECD, EAS (MSTI database), April 1997

4 Service Bulletin, *Science Statistics*, Statistics Canada, 21(8):4.

Federal Government Health Research Funding per Capita		
	Canada	U.S.
Year	MRC total funding per capita (C$)	NIH total funding per capita (C$)
1990–91	$8.71	$39.71
1992–93	$8.98	$47.35
1994–95	$9.09	$57.41
1996–97	$8.40	$61.64
1997–98	$8.23	$66.64 (E)

Source: Medical Research Council. (E) Estimate

The long-term impact of falling R&D investment on the technological capacity of the Canadian biotechnology industry is staggering. Consider medical research, the genesis of most leading-edge practices in biotechnology as an example. In the United States, the budget of the National Institutes of Health (NIH) rose by 16.3 per cent between 1994 and 1997 to reach US$10.7 billion. The goal of the U.S. Senate is to see the NIH budget double over the next five years.[5]

In the same period of 1994 to 1997, the budget of the Medical Research Council of Canada declined by 10.7 per cent to C$238 million. To put this in some perspective, Canada's MRC budget is now about 1/45 that of the NIH[6] when the traditional ten-to-one benchmark would indicate MRC funding should be US$1 billion.

To its credit, the federal government has begun to recognize that Canada's research enterprise is suffering. Two recent announcements, the Canada Foundation for Innovation and the permanent establishment of the Networks of Centres of Excellence program, are significant first steps. However, there is a third element of a renewed strategy for support of research: it must also include strong and rapid reinvestment in the base budgets of the federal granting councils.

Funding for the granting councils has dropped throughout the 1990s. In 1998, funding for MRC, NSERC and SSHRC will be lower than in 1985. This is particularly damaging since the three councils support the majority of research performed at universities, teaching hospitals and affiliated research institutes across the country.[7] Thus, there is a serious funding gap.

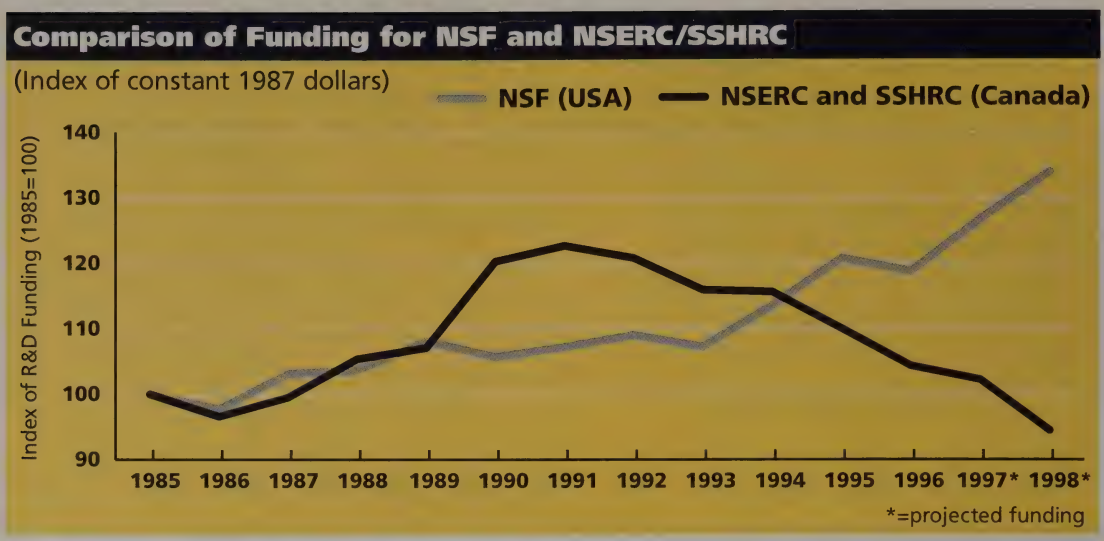
Federal Government Health Research Funding – Canada vs US					
Budgets	1994–95	1995–96	1996–97	1997–98	1998–99
NIH Extramural (US$millions)	9,071	9,400	9,900	10,708	10,855
MRC (C$millions)	266	250	242	238	221

Source: Medical Research Council

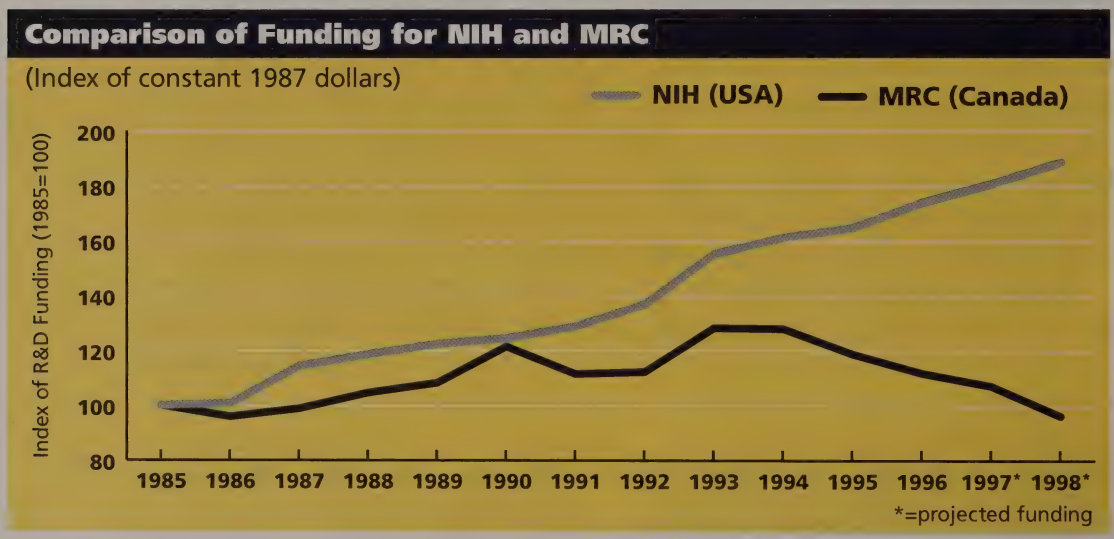
5 Information provided by the Medical Research Council, January 1998.

6 MRC 1997/98 *Main Estimates*, Part III Expenditures Plan, p.15.

7 *Keeping the Balance: Security and Opportunity for Canadians*, Report of the Standing Committee on Finance, December 1997, p. 34.



Source: *Keeping the Balance: Security and Opportunity for Canadians*, Report of the Standing Committee on Finance, December 1997



Source: *Keeping the Balance: Security and Opportunity for Canadians*, Report of the Standing Committee on Finance, December 1997

The House Standing Committee on Finance has, for three consecutive years, called with increasing urgency for significantly strengthened funding to the federal granting councils, and a long-term commitment to that goal.

Waning federal government funding of university-based, curiosity-driven research is not being compensated by increased public sector support. If this gap is not addressed, Canadian biotechnology runs the risk of not realizing its commercial goals, to the detriment of long-term competitiveness.

Indeed, we would submit that Canada is already witnessing the consequences of this reduced funding. Despite Canada's historical strength in medical genetics, we do not have in this country any broadly based genomics company, the Canadian equivalent of the U.S. Human Genome Sciences, Millennium Pharmaceuticals, or Incyte Pharmaceuticals. We believe it is too little, too late for any comparable Canadian genomics company to take root and flourish. The absence of any significant commercial presence in genomics, by way of illustration, is a direct

Recommendation

In further support of the recommendations of the December 1997 Report of the Standing Committee on Finance, NBAC recommends that the federal government reinvest in the budgets of federal granting councils to double the 1993–94 level of support within three years, by 2001, and triple the 1993–94 budget in five years, by 2003. New funding should be directed primarily to molecular sciences.

consequence of our failure 10 years ago to invest appropriately in the interdisciplinary sciences needed to catalyze and support substantial genomics companies.

If Canada is to be successful in consolidating a position of leadership in biotechnology, it must be effective in counteracting the current forces that have already begun to erode its science base.

Recommendation

NBAC recommends that the federal government advance postgenomic studies through increased funding to Canada's genome program, with a strong emphasis on functional genomics, bioinformatics, proteomics, domain studies and differential gene expression including allocation to Medical, Ethical, Legal and Social Implications (MELSI) research.

3.2

Technology Transfer: Linking the Precommercial Science Base with Industry

Technology transfer is a contact sport. Networks are critically important. A strong science base with effective links to industry that capture and exploit the economic benefits of leading-edge research is a formula for a vibrant and successful biotechnology industry in Canada. Successful technology transfer is predicated on a number of factors, which include the effective two-way exchange of both people and ideas between science and industry, the ability to identify opportunities of mutual value to both the scientist and the business person; and a Canadian industry receptor base, with a critical mass capable of value capture.

"With targeted growth strategies, we will build those knowledge-intensive sectors where we are strong and where the opportunities for growth and global leadership is highest. Examples are... biotechnology in agriculture and fisheries.... In particular the Government will significantly increase the resources allocated to help small and medium-size business develop and commercialize new technology."

Speech from the Throne to Open the First Session, Thirty-Sixth Parliament of Canada

NCEs: A Canadian Success Story

As part of their mandate to build partnerships among universities, industry and government as a stimulus for fundamental and applied research, the Networks of Centres of Excellence (NCE) have produced a substantial amount of intellectual property that was made available for commercialization. By investing in areas that have strategic importance to Canada, the Networks produce significant research discoveries and innovations, ensure that they are transferred quickly to potential industrial users and public policymakers, and train highly qualified researchers, often in settings outside the university.

On October 3, 1997 the government announced that seven of the existing Networks would receive additional funding totalling $94.3 million over the next four years. Three of these seven Networks are health-related, addressing issues ranging from myotonic muscular dystrophy and juvenile diabetes to the use of protein engineering to improve the effectiveness of medications and develop new vaccines.

Many of the Networks have established commercialization vehicles to manage the protection and licensing of intellectual property as well as multi-party research-collaboration agreements between industry and network members. In 1996–97, approximately 800 organizations were involved in the NCEs, including 445 companies, 48 universities and 130 government departments and agencies. In this same period, 135 patents were filed, 40 patents were issued and 58 licences were granted to industry. The NCEs have spun off 43 companies, of which 25 are health-science-related.

Through a competitive process 25 per cent of the NCE budget is made available for the development of new networks. Strong consideration should be given to the development of an agricultural biotechnology NCE. ■

Source: Networks of Centres of Excellence (NCE) Web site *http://www.nce.gc.ca*; NCE Press Release Oct. 3, 1997; NCE 1995 Annual Report

3.2.1 Canada's Universities are Beginning to Master Technology Transfer

Effective technology transfer comes down to having the right people in place to recognize the potential of a new idea and to translate it to the appropriate industry. It can be viewed as a flow of information first within the academic community, then between university and industry, and finally from one industrial segment to another. Ultimately, the success of technology transfer is judged by how effectively the knowledge arising from university and federal research is captured and converted into economic gains.

How does technology transfer start? Which factors limit diffusion and industrial uptake? Can we learn something about why the technology transfer from university to business in Canada has lagged behind that in the United States, the acknowledged leader?

Now that Canada's venture capital situation has begun to improve, any future lag in technology transfer can be attributed only to obstacles of attitude or a lack of experience. American scientists involved in start-ups appear to be comfortable with the concept that business principles must prevail if the company is to reach commercial success. University scientists in the United States are more entrepreneurial and less prone to think that they should not stray from the cloistered halls of academe. American academics have learned that "It's okay to make money."

In Canada, universities are beginning to regard their technology-transfer offices as a resource and as a way of paying back the nation for its investment in research — first, as a vehicle to help faculty members realize ambitions that lie beyond the research laboratory, and second, as a means of generating funds that can be put to excellent use in helping universities achieve academic goals that may not be possible otherwise.

Efficiency of Technology Transfer: A Canada/US Comparison[1]

How good is Canada at recognizing the potential of a new discovery and commercializing it?

	United States	Canada
% Royalties Received[2]/Total R&D Expenditures[3]	1.83%	0.85%
Royalties Received/FTEs[4] (US$)	$279,120 per FTE	$51,662 per FTE

U.S. universities, research institutes and hospitals are twice as effective at getting industrial uptake of their patented ideas (royalty revenues per dollar of research funding). Further, on a per-capita basis, U.S. technology transfer professionals are more than five times as effective as their Canadian counterparts. ■

1. Universities, hospitals and research institutes

2. Less royalties paid to other institutions and net of legal fees

3. Includes research expenditures from the federal government, industry and other sources

4. Full-time Equivalents (FTEs) include both specialists and other employees engaged in technology transfer and licensing activities

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University scientists are becoming much more receptive to the idea of business links, and are learning that the business of biotechnology is different from research.

Technology transfer is a complex and knowledge-intensive process. Experienced individuals with widespread contacts and the necessary resources in an environment that actively supports technology transfer are the keys to success. Mechanisms include joint business — government-funded research centres that support university researchers. Other mechanisms include incentives that permit a two-way flow of researchers between universities and industries and the inclusion of universities as active participants in industry clusters. Building on such a framework, NSERC introduced its University-Industry Programs to provide training for technology transfer officers and expand human resource capacity.

Incubators that include technology transfer specialists and venture capital experts have proven successful in Quebec. Other incubator formulae have worked well in Ontario. The Finnish formula of joint industry/university technology centres outside the formal university structure has proven very successful in developing knowledge-based products of outstanding quality; this approach is now also beginning to demonstrate its strengths in biotechnology.

Recommendation

NBAC recommends that technology transfer be strengthened in Canada in the following ways:

- **university technology-transfer offices undertaking an international benchmarking exercise and developing a program of global best practices**
- **university technology-transfer offices developing mechanisms such as standard but flexible formats for licensing and cooperative research and development agreements**
- **the federal government assisting with a full inventory of networks linking universities, industry, venture capitalists and business experts, in addition to the Canadian Technology Network, with a view to making them more accessible and strategic in focus**
- **governments assisting smaller universities, which have limited technology-transfer capability, with their patenting and commercialization.**

3.2.2 University-company Biotechnology Successes

If the value of Canadian research is to be captured effectively in Canada, there must be a base of industrial receptors capable of commercialization. Canada's industrial base is quickly gaining the critical mass necessary to successfully take ideas from the laboratory and convert them into products for the marketplace. Successful start-up companies, some spawned directly from the activities of university researchers, have become established in recent times. Examples include StressGen, GlycoDesign and Visible Genetics. These demonstrate to risk-capital groups, university scientists and university administrators that the Canadian academic scene is a fertile source of biotechnology ventures. Furthermore, they show that mutual benefit can be gained by all groups that participate in a fruitful start-up company. Yet with all these improvements, there remains a substantial barrier to the smooth transfer of technology between universities and industry — the gap between discovery and proven commercial potential.

Spinoff	University	Product
Biomira	University of Alberta	**Truquant** and **Tru-Scint:** allow early diagnosis and identification of cancer sites **Theratope** and **BPI-7:** therapeutic vaccines designed to stimulate the immune system to combat cancer
Microtek International Ltd.	University of Victoria	Vaccine to protect salmon from furunculosis (a disease that causes losses of up to 50% of salmon stock in North America, Scotland, Ireland, and Norway) is ready for field trials
Phero Tech Inc.	Simon Fraser University	**Fruit Boost:** bee pollination enhancement product for use in orchards and berry crops Develops other semiochemical-based (i.e. pheromones) pest management products, particularly for forestry
Biostar Inc.	University of Saskatchewan	Cattle vaccines **Pneumo-StarTM:** prevents infection by *Pasteurella haemolytica* **Somnu-StarTM:** prevents *Haemophilus somnus* disease complex **Sommu-Star phTM:** combination of the first two vaccines
Nexia Biotecnologies Inc.	McGill University	**Mac-T:** a gene-screening system, along with gene transfer technology, aimed at enhancing the composition of milk, enabling the design of specific value-added dairy products and improving the production of processed dairy foods
QLT Phototherapeutics Inc.	University of British Columbia	**Benzoporphyrin Derivate (BPD):** light-activated drug to treat cancer, psoriasis and age-related macular degeneration (leading cause of blindness in the elderly); upon injection, BPD accumulates more in diseased than in healthy tissue. When a special light is shone on the diseased tissue, BPD releases a toxic form of oxygen that kills the cells.

Source: Canada Foundation for Innovation

In a study by NRC of 480 university spinoff firms in Canada, more than 150 are in life sciences (biotechnology/medical). These firms created 9,300 jobs in 1995 alone and $1.3 billion in sales. The sales of the life sciences group of firms are proportionately lower primarily because of the number of firms that are still in the R&D stages. However, the university spinoff firms in life sciences attracted $1.2 billion of the $2 billion raised by all biotechnology firms in 1991–96.[8]

Canadian Medical Discoveries Fund and University Medical Discoveries Inc.

The MRC-inspired Canadian Medical Discoveries Fund (CMDF) is a labour-sponsored venture capital company investing in early-stage and even precommercial health research ventures. In less than three years, CMDF has become Canada's leading investor in biotechnology, having driven the transition of Canada's biotechnology industry from being venture-capital-poor to being one of the world's richest. With more than $260 million raised and more than one half of that already committed, CMDF is helping to create the new companies, such as Apoptogen and Terragen Diversity, that are leading the recent explosion of growth in Canada's biotechnology industry. In addition, CMDF has helped repatriate lost Canadian technologies and researchers, and to reverse the flow of the brain drain through newly Canadian companies like Vascular Therapeutics in Hamilton.

One of the earliest CMDF investments was in the work of two academic researchers based at the University of Ottawa and working out of the Children's Hospital of Eastern Ontario. Recognizing the extraordinary potential of the research being undertaken by Alex MacKenzie and Robert Korneluk, CMDF helped them create Apoptogen, and provided the necessary funds for patenting and company creation. This experience made obvious the fact that an investment vehicle was required for even earlier stages than CMDF was built for, and thus University Medical Discoveries Inc. was born.

University Medical Discoveries Inc., known as UMDI, funds research projects that are still at the bench stage in academic research labs. The company provides the resources to protect and develop the discovery far enough to add significant value, before transferring it to a commercial partner or creating a commercial entity, which must then be valuated. UMDI acts at the earliest stage of technology transfer, when Canadian researchers have traditionally been forced to turn to foreign companies for development financing. This is the stage at which Canada had been losing ownership of most of its best research, and losing, in turn, the return on its research investment.

The government-industry partnership between MRC and CMDF has proven extremely successful at building relationships between Canada's academic-based researchers and its business community. Other federal agencies have expanded the model well beyond the health sector.

The year 1997 saw the launch of the Science and Technology Growth Fund, a sister fund to CMDF, championed by the Natural Sciences and Engineering Research Council, the National Research Council and the Canadian Space Agency in partnership with the private sector. These collaborative efforts are ensuring that Canada's investment in fundamental research is producing health and wealth benefits for Canadians. ■

8 Information provided by National Research Council, Industrial Research Assistance Program.

3.2.3 The Developmental Gap: The Post-idea/Pre-company Niche

University inventions need, typically at an early stage, additional research and development to prove their commercial potential. Substantial amounts of time and money must be invested in order to spark industrial interest by demonstrating whether the technology is commercially viable. In Canada, there is a developmental gap for seed capital at this stage — too early for the traditional sources of venture capital or ineligible for the available government programs (e.g. Technology Partnerships Canada and the Industrial Research Assistance Program).

Recommendation

NBAC recommends that the government encourage more initiatives similar to UMDI, the preferred model, to assist in addressing the financing gap at the post-idea stage. As an additional strategy, government programs, such as those of the Natural Sciences and Engineering Research Council and the Medical Research Council, in partnership with industry, should be encouraged to help researchers prove the potential for commercial application and demonstrate the business case for their discoveries in the "post-idea/pre-company niche."

However, there are promising new sources of developmental funds. Two excellent examples are the University Medical Discoveries Inc. (UMDI), associated with the Canadian Medical Discoveries Fund (CMDF), and the Canadian Science and Technology Growth Fund (CSTG). UMDI and CSTG funds are targeted at Canadian university research demonstrating promise for commercialization but requiring extensive development before an accurate assessment can be completed. Fund representatives work directly with the innovating researcher to bring promising discoveries to the next funding stage. More funds of this kind would speed the process of technology development.

3.3 An Immature Receptor Base: Problems of Keeping Technology Canadian

University technology-transfer offices are generally free to license technology worldwide. All too often, Canadian biotechnology goes offshore because Canadian companies, as a result of the developmental gap or because they lack the expertise and confidence, are unwilling to invest in higher-risk, early-stage technologies. Prosperity depends on industry, academia and government building on regional strengths to create unique high-value-added products. Uniquely Canadian solutions, such as the Networks of Centres of Excellence and regional clusters, are needed to lever the industrial base and encourage technology transfer between industry and academia.

Recommendation

NBAC recommends that municipalities, provinces and the federal government work with other stakeholders across Canada to increase support for mechanisms such as regional clusters, bio-incubator facilities and Networks of Centres of Excellence that function to lever funds for and develop a Canadian industrial base.

3.4
The Shortage of People

Ultimately, the success of Canadian biotechnology depends on the availability of a highly skilled and motivated work force. In the various phases of biotechnology as it progresses from a focus on R&D to one of commercialization, the industry has different human resources requirements. Biotechnology is unusual in that it requires people familiar with subject matter that crosses traditional disciplinary boundaries. Not only does the industry need traditional technical expertise in areas such as molecular biology and molecular pharmacology, but it also requires experts in government regulations, patenting, manufacturing, finance and management.[9] In particular, Canadian scientific entrepreneurs are in desperately short supply.

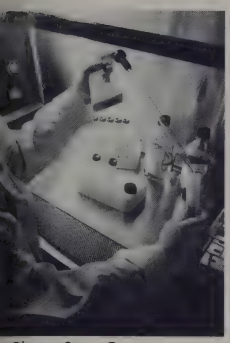

Photo: StressGen Biotechnologies Corp.

The recent Paget study[10] highlighted areas in which Canadian firms are understaffed. In the short and medium term, universities and community colleges will be able to meet the demand for scientific and technical personnel. However, there will be a shortfall in the number of people with backgrounds that combine several scientific specialities, such as peptide chemistry, gene therapy, bio-informatics, production scale-up and formulation, which is exacerbated by the emigration of key researchers, as the table on the right shows.

Migration of Star Researchers

Universities and research institutes are a primary source of exploratory research. Cuts in federal funding and the weakening of granting councils are beginning to undermine Canada's traditionally strong scientific base. With aging and obsolete infrastructure and decreased program funding, it is becoming increasingly difficult to attract and keep world-class researchers.

To illustrate this trend, up to 1990 (the most recent compilation of statistics) Canada has lost 30 per cent of its star genetic researchers. The long-term downward spiral due to the loss of top scientists is vicious. In the formative years of a high-technology industry, success depends on the motivated participation of a small number of extraordinary scientists with vision and mastery of ground-breaking technology. The very best scientists are crucial to affecting both the pace of scientific diffusion, and the timing, location and success of its commercial applications. ■

Country	Net Migration Rate
	(%)
United States	2.9
Japan	9.6
United Kingdom	32.3
France	4.0
Germany	8.3
Switzerland	-40.0
Australia	7.1
Canada	**-30.0**
Belgium	14.3

Source: Lynne G. Zucker and Michael R. Darby, *Star Scientists and Institutional Transformation: Patterns of Invention and Innovation in the Formation of the Biotechnology Industry*, Proceedings of the National Academy of Sciences, November, 1996, Vol. 93, p.12,715.

9 Human Resources Development Canada, *Building Long-Term Capability Now: Canadian Human Resources Study in Biotechnology*, Executive Summary, May 1996.

10 Department of Foreign Affairs and International Trade, *A Comparative Overview of National Biotechnology Strategies*, DFAIT 1997, p 19.

The Paget study pointed out in particular a severe lack of experienced entrepreneurial and business-development talent. The Canadian biotechnology industry is not yet sufficiently large or mature to provide a fertile breeding ground for home-grown entrepreneurial talent. Small companies[11] account for 72 per cent of Canada's biotechnology industry, and large companies (a traditional source of entrepreneurial and managerial talent for start-up companies) account for only 11 per cent. This, coupled with the regional nature of the Canadian biotechnology industry, results in an inadequate corporate training ground for broadly based business talent.

Recommendation

To encourage entrepreneurs and would-be entrepreneurs to pursue innovative ideas and products, NBAC recommends that Industry Canada do the following:

- **develop a "virtual network" to allow like-minded individuals to network and link with successful industry mentors and business/managerial information sources and provide the platform for an employment/recruitment network that reaches out to expatriate Canadians.**

Industry, business schools and colleges should do the following:

- **develop undergraduate programs and an apprenticeship/internship program at the postgraduate level to give science students vital business experience.**

To address the more urgent short-term issue of skills shortage, NBAC recommends that Citizenship and Immigration Canada do the following:

- **expedite the fast-track immigration process for biotechnology scientists and technology-transfer specialists.**

As a consequence, people with a scientific background find relatively few opportunities for training and mentoring in the entrepreneurial and development side of the biotechnology business. Pasteur-Mérieux-Connaught and other Canadian industry pioneers have seeded the next generation of biotechnology companies with scientists and general managers, but the talent pool remains small.

Banks, investment institutions and venture capital organizations are also experiencing a severe deficit of qualified personnel with both scientific and business expertise to advise on technological investment. This has the further consequence of reducing the number of knowledgeable potential investors in young biotechnology companies.

In response to the needs identified in the HRDC Report, the Biotechnology Human Resources Council (BHRC) was inaugurated on April 1, 1997. A joint initiative between Human Resources Development Canada and the Industrial Biotechnology Association of Canada, the BHRC has identified five main target audiences that require different skills, knowledge and training, and is developing programs and initiatives to meet their immediate needs. These target audiences are research/technical biotechnology professionals, non-technical biotechnology professionals, university and college faculty, secondary school teachers and government regulators. In addition, the BHRC will be working with Citizenship and Immigration Canada and Human Resources Development Canada to streamline and facilitate the immigration of individuals with needed biotechnology-related skills.

11 Ernst and Young, *Canadian Biotech'97: Coming of Age*, p 2.

While it is not possible to teach people to be entrepreneurs, it is possible to provide the fertile environment in which entrepreneurs are self-selected and nurtured.

Factors Contributing to Mobility of High Technology Talent, in Order of Importance

1. Level of compensation offered by the firm
2. Aggressive recruitment techniques
3. Taxes
4. Other*
5. Lack of training and development opportunities
6. Incompatibility with culture of firm
7. Quality of life

* Responses to "Other" included career path not meeting the needs of employees, difficulties with immigration process, political instability, lack of challenge, uncertainty caused by long period of restructuring, and lack of "new" technology.

Source: The Conference Board of Canada, *Recruiting and Retraining High Technology Talent in Canada: A Business View*, May 29, 1997, Part 2, p. 3.

"World leadership in the growth industry of the next century is ours to lose."

Hugh Wynne-Edwards

Our Future Human Resource Pool

Lessons learned in other high technology industrial sectors suggest that focussing only on recruitment from abroad is at best a short-term solution as a means of compensating for the lack of biotechnology business expertise in Canada. It is the youth of today who will be the scientists of tomorrow. Canada's educational system should do more to promote a science culture and build awareness among young Canadians of the existing career potential that life sciences offer.

Initiatives such as Agriculture in the Classroom, supported by Alberta Agriculture, Food and Rural Development, reach out to children in the classroom from grades 6 to 12 with posters, videos, resource manuals/workbooks, computer programs and specialist speakers. These classroom outreach programs and others such as science camps, like Camps Écoles en Biotechnologie run by Collège de Rivière-du-Loup, newsletters and board games provide Canadian youth with a valuable scientific base, demystifying biotechnology.

Recommendation

NBAC recommends that industry, government and educators work together to ensure that Canada's youth are aware of the exciting careers in biotechnology, and that classroom outreach and alternative educational mechanisms are expanded and vigorously supported to strengthen "science culture" in Canada and, in particular, awareness of biotechnology.

Market Access, Intellectual Property Rights and Regulation

CHAPTER 4

ABSTRACT Canada's intellectual property (IP) rights and regulatory frameworks have been enhanced in many respects since the recommendations tabled in NBAC's 1991 report. However, some changes are still required in order to bring Canada's IP protection practices as well as health, safety and environmental regulations in line with those of its major trading partners to enhance competitiveness. On the regulatory side, the Committee believes that regulatory efficiency and transparency are important to competitiveness and public confidence. While clear strides have been made, more can be done to benchmark our performance vis-à-vis our competitors and to expand international cooperation. Finally, market access issues have arisen in the context of international trade in products of biotechnology; these issues require attention and action.

4.0 Introduction

Government rule making is a critical factor in the ability of a nation to capture value from scientific endeavour. Thus, we believe that regulations governing health and safety and the environment — if they are based on rigorous science, procedural transparency and timeliness — confer significant competitive advantage. Science-based products and services have value-added because of the intellectual property embodied in them. Accordingly, we also believe that one cannot build a world-class innovative biotechnology sector on intellectual property protection that is less robust than the protection offered by Canada's major competitors and trading partners.

4.1 International Market Access

The number of genetically modified crops entering international trade as basic food items is rapidly increasing. Some countries are experiencing difficulty regulating these products. In fact, outside the technically advanced countries, relatively few have a comprehensive regulatory framework in place.

Those that do have regulations have made limited attempts to ensure those regulations are complementary or similar to those of their major trading partners. For example, in the agriculture sector, even though in some instances the *same data* may be accepted in many countries to assess products, the *decisions rendered may differ.* Products approved in one country may be put on hold or refused market access in another, sometimes for political reasons rather than for strictly science-based, health and safety, or environmental safety reasons. Transactions in genetically modified commodity crops can be delayed for months or even years. Continuation of these trends can only harm Canadian biotechnology companies, which must export to survive.

Foreign import regulations for approved genetically modified agricultural and other products are of vital importance to the Canadian ag-bio and biopharma industries. Most technically advanced countries have in place regulations governing the import of products of biotechnology. In fact, the Organization for Economic Cooperation and Development (OECD) has developed principles and guidelines over the past decade as a basis for national regulatory structures for the control of products of biotechnology.

Photo: National Research Council

Sound scientific assessments of product risk were agreed upon as the major fundamental principles of these national regulatory structures. Canada has been at the forefront in the development of these principles and guidelines, both at the OECD and other international organizations such as the World Health Organization and the Food and Agriculture Organization.

The United States, Japan and the European Union, as well as Canada, all have in place similar regulations, based on national interpretations of guidelines developed in these fora. In addition, the WTO has indicated that decisions barring imports of products of biotechnology on any basis other than valid scientific evidence would be considered non-tariff trade barriers.

Despite all these discussions and negotiations in international fora, and notwithstanding the best and continuing efforts of the Department of Foreign Affairs and International Trade (DFAIT), transgenic canola, produced and approved for use in Canada and for export to Japan and the United States, is still awaiting approval for import into the European Union. This is after more than three years in the regulatory process when three separate scientific review bodies found there to be no safety reasons to refuse approval of these canolas.

Recommendation

NBAC recommends that Canadian trade negotiators 1) insist upon strict adherence to World Trade Organization disciplines by Canada's trading partners, 2) use vigorously, when appropriate, the trade remedy and dispute settlement procedures available under the General Agreement on Tariffs and Trade (1994), and 3) push energetically in the longer term for trade liberalizing solutions in which trade barriers are invoked on science-based risk assessment only.

It is now clear that approval of some canolas is being delayed on political rather than scientific grounds, especially in view of the fact that both transgenic soybean and corn were given approval for import after a relatively short time.

4.1.1 International Harmonization of the Regulation of the Products of Biotechnology: Mutual Recognition Agreements and Joint Product Reviews

In those instances when the market access problem is linked to regulatory evaluation, two possible solutions have been proposed that could be put into effect within a short time period to achieve cost savings and improve the speed of product assessment.

The first proposal recommends that countries dramatically expand the practice of joint reviews. Under this agreement, national bodies would review the same data packages simultaneously, comparing notes and views as the review progresses. In this way, regulators would gain from each others' complementary expertise, leading to more efficient assessments of new products plus a speedier introduction into international markets. While this practice is currently in use and paid for by companies, it is not well known and should be written up in the guidelines and communicated more widely to the industry.

Recommendation

NBAC recommends that federal departments with responsibility for the regulation of products of biotechnology examine, with their counterparts in Canada's major trading partners, ways of conducting joint reviews of product data packages and working towards mutual recognition of product regulatory reviews.

In addition to joint reviews, a second proposal would work towards mutual recognition through greater international harmonization of product approval requirements (i.e. data, filing and submission formats, and the regulatory process itself). As an example of harmonization efforts, Health Canada initiatives to design a modified Food and Drug Administration filing format for use in Canada should be accelerated and emulated. In the longer term, it is not unreasonable to expect mutual recognition of product approvals, since most industrialized countries have the common objective of safeguarding the health of their population and the environment and have sophisticated regulatory regimes to achieve these goals.

4.1.2 Biosafety Protocol for Transboundary Movement of Living Modified Organisms

Modern biotechnology has the capacity to introduce a greater diversity of genes into organisms, including genes from unrelated species. Traditional methods of breeding and selection do not have this capacity. Organisms genetically modified in this way are referred to as Living Modified Organisms (LMOs). Many developed countries with biotechnology industries have domestic legislation already in place to ensure the safe transfer, handling, use and disposal of LMOs and their products. These precautionary practices are collectively known as "biosafety." However, there are no binding international agreements covering the movement of LMOs across national borders.

At the Earth Summit in 1992, Canada and more than 120 nations signed the Biodiversity Convention. The United States was not a signatory to the Convention on grounds that it would compromise the country's national integrity and ability to manage its resources. Subsequently, the U.S. has signed but has not yet ratified the Convention. One of the outcomes of the Convention is the decision to draw up a binding international protocol that would require prior notification and approval of the intent to export LMOs. Since transgenic crop seeds could be considered to be LMOs,

this protocol, once in place, might affect all international trade in commodity crops, since most major crops will be derived in part from transgenic seed in the near future.

Recommendation

NBAC recommends that Canada's science-based regulatory system, together with agreements in place with Canada's trading partners, be used as the basis for the protocol on transboundary movement of Living Modified Organisms. Industry Canada and the Department of Foreign Affairs and International Trade should work to ensure that the Canadian negotiators strongly resist any attempts by other nations to make the Biosafety Protocol an additional regulatory burden on those countries that already have regulatory systems in place for these products.

The Conference of Parties of the Convention on Biological Diversity established a *Biosafety Working Group* to seek a solution to the concerns related to biosafety through the development of a protocol. The protocol was designed to focus specifically on the transboundary movement of LMOs resulting from modern biotechnology that may have an adverse impact on the conservation and sustainable use of biological diversity. It would also set out appropriate procedures for obtaining *Advance Informed Agreement*. Many countries, however, have neither the regulations in place nor the capacity to enforce them. Such shortcomings render a protocol impracticable without some international system in place capable of monitoring movements and ensuring enforcement. At present, no such system exists. Nor is it clear what competence and authority it would have if it did exist.

A biosafety protocol could add little positive value to the regulation of products that are already effectively regulated at the national level. However, the industry acknowledges that a transparent, predictable, science-based approach to the transboundary movement of LMOs, if implemented properly, could benefit exporters by enhancing consumer confidence, particularly in emerging markets. Strong representations have already been made by Canadian industry to negotiators that the Biosafety Protocol should not become yet another regulatory barrier that impedes trade in Canadian products. A more constructive approach is suggested in the recommendation opposite.

4.2 UNESCO's Universal Declaration on the Human Genome and Human Rights

Another international instrument, the United Nations Educational Scientific and Cultural Organization's (UNESCO) Universal Declaration on the Human Genome and Human Rights (DHGHR) has the potential to become an international convention. This Declaration is the first international text on the ethics of genetic research. As such, it requires careful examination by both the biotechnology industry and government policy makers. Its provenance is as follows.

In 1993, the General Conference of UNESCO approved the establishment of the International Bioethics Committee (IBC). The Committee was appointed to a four-year term (1993–1996) by the UNESCO Director-General, and was asked to develop an international standard-setting instrument to protect the human genome. In 1995, the General Conference invited the Director-General to draw up a preliminary draft declaration with a view to its adoption by

Recommendation

NBAC recommends that Industry Canada work with the Department of Foreign Affairs and International Trade and actively participate in the follow-up to the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights and participate in the ad hoc working group to bring to the process the balanced perspectives of science, research, consumers and commercialization that the industry portfolio of the department represents.

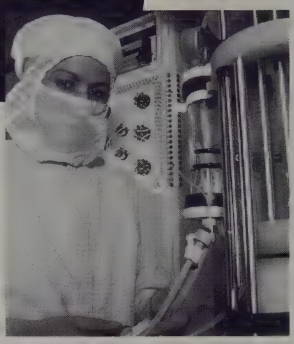

Photo: National Research Council

the General Conference in November 1997. A committee of governmental experts was convened in July 1997 to review and finalize the preliminary draft prepared by the IBC. This committee adopted the draft by consensus. Canada, however, identified for the committee the following areas of concern: commercialization, intellectual property rights, privacy protection and the need for domestic consultation with affected groups.

Nevertheless, the General Conference of UNESCO adopted the Declaration in November 1997. However, the resolution that accompanied the adoption of the declaration called for the formation of an ad hoc working group of government representatives reporting to the Director-General to make recommendations on the composition, mandate and breadth of consultation of the IBC. Each of these three aspects requires careful deliberation. It is important in these next steps that research and commercialization aspects are considered, alongside the environmental, human rights and socio-ethical issues.

4.3 Intellectual Property Protection

In its 1991 report, NBAC made recommendations to the Minister regarding IP protection. Since then, the government has taken action and responded to several of NBAC's concerns.

- The Patent Office, renamed the Canadian Intellectual Property Office (CIPO), became a Special Operating Agency, and has successfully recruited additional patent officers specifically to reduce the backlog of unexamined patents and to examine new biotechnology patents.
- The *Patent Act* was amended to allow the deposit of unicellular life forms in internationally recognized depositories, and Canada became a signatory to the Budapest Treaty.
- The time within which a patent applicant has to request an examination has been reduced from seven years of the initial filing date to five years. As a result, the number of unexamined patent applications has been reduced, providing greater certainty for Canadian business.

However, there remain significant steps that still can be taken to improve the reliability, scope and quality of Canadian patents.

4.3.1 Plant Breeders' Rights

The *Plant Breeders' Rights Act* gives developers of new plant varieties control over the multiplication and sale of reproductive materials of the new variety. To receive protection, a plant variety must be distinct, uniform and stable. The Act provides the

developers of plant varieties with an opportunity to recover investment in research. The rights include the ability to charge a royalty and to control the sale of propagating material. Users who do not remit royalties or who sell a protected variety for propagating purposes may be prosecuted by the holder of the right or its agent.

The Act protects only some species — currently 45 are protected. Regulations covering forest and tree species have yet to be formulated under the Act, although protection for new varieties in this category is under review by the plant breeder's office.

Recommendation

NBAC recommends that Canada bring its regulations regarding Plant Breeders' Rights into line with the 1991 UPOV Convention and promote the ratification of that convention (or equivalent minimum plant breeder protection) among its trading partners.

Although Canada ratified the 1978 UPOV (International Union for the Protection of New Varieties of Plants) Convention, it has not yet ratified the 1991 UPOV Convention. The 1991 Convention extends coverage to "essentially derived varieties and to harvested materials," a significant improvement over the previous UPOV. Several countries have modified their regulations to conform with the 1991 Convention even though, to date, fewer than five countries have actually ratified it. Nevertheless, the 1991 Convention marks a significant advance, and NBAC considers it important for Canada to bring its regulations into line with the extended scope.

4.3.2 Obligations Under the World Trade Organization

Under the Trade-Related Intellectual Property (TRIPS) treaty of GATT now enforced by the WTO, Canada is committed to put forward proposals that will bring its IP protection system into closer alignment with that of the other signatories to the treaty or provide cogent reasons why it should not do so. In January 1999, the WTO will begin a review of the provision in the TRIPS text relating to the protection of higher life forms.

Canada is a member of the world IP system established by various conventions such as the Paris Convention, the UPOV Convention (mentioned previously) and the IP provisions of the WTO (formerly GATT). The overriding concern of Canadian industry is to have open and fair access to world markets and also to ensure that Canadians can receive adequate protection for their IP in the important markets of Europe, the United States and Japan. The trade-off for this is that Canada must provide adequate IP protection for its trading partners in order to expect to be given the same privileges in the far larger markets outside of Canada. A country does not provide IP protection to foreigners for altruistic reasons; it provides that protection to guarantee access for its own important inventions in foreign markets. This should not be lost sight of in the context of the following discussion.

Three areas remain in which Canada's patent rights still differ from those of most developed countries. The first is the patenting of multicellular life forms (i.e. plants and animals). The second is in the area of Patent Term Restoration (PTR). The third is that Canada has no procedure for opposing patents once they have been issued.

Patenting of Higher Life Forms

Unlike the U.S. and Europe, no patents on either plants or animals have been allowed in Canada. Claims to a non-human mammal in the patent application for the Harvard Onco-Mouse were refused by the Commissioner of Patents in August 1995. An appeal was being heard in the Federal Court of Canada Trial Division in November 1997 as this report was being prepared. The extension of patent protection to multicellular life forms is a matter that is extremely difficult to legislate. In fact, the decisions upholding patents for animals in other jurisdictions (i.e. U.S., Europe, U.K.) were all made by the courts on the basis of existing laws. We are hopeful that, as in other countries, the Canadian court will adequately define the boundaries. If it does not, however, it will be necessary for Canada to work within the WTO to produce a consensus view with its trading partners, which should result in strengthened patent protection in Canada for multicellular life forms. These matters will be addressed by the WTO in January 1999.

Reducing Regulatory Delay or Offering Patent Term Restoration

Biotechnology inventions to be used as drugs are subject to considerable regulatory delay. A product must pass a series of rigorous clinical trials to ensure its safety and efficacy and the validity of health-related claims made about the product. Canada's major trading partners offer the option to restore some of the patent time lost in the regulatory process under certain specific circumstances. In contrast, Canada does not offer patent term restoration. The implications of this in regard to the commercial benefit to Canada should not be ignored.

Recommendation

NBAC recommends that the federal government study the intellectual property rules of Canada's major trading partners and, within the framework of the World Trade Organization, take the necessary steps to ensure that Canada's intellectual property rules provide the same support to commercialization as those of other signatories of the General Agreement on Tariffs and Trade (1994).

Broad Patenting Without Corresponding Utility

A recent trend has emerged to patent naturally occurring gene sequences regardless of any known utility. Thus, it is possible for these genomic patents to effectively stake out and claim all known gene sequences, in the hope that eventually a utility will be found by which the patentees can profit.

Patent law has long required that an invention disclose a utility and be "enabled." This is so in Canada, the United States and Europe (although utility is sometimes referred to as "industrial applicability"). Whatever the terminology, it is likely that the current statutory regime, if properly interpreted, will limit attempts to stake out claims to naturally occurring gene sequences without a discovered utility or industrial applicability. However, because of some precedents in the United States, NBAC urges that CIPO defend the principle of utility and ensure that it prevents claims without specific utilities, which could unjustifiably restrict industrial development in Canada with no corresponding benefit, by way of a properly described, enabled and useful invention.

Recommendation

NBAC recommends that the Canadian Intellectual Property Office take note of industry concerns and not allow claims to naturally occurring "sequences with no legitimate utility" or "industrial applicability" that could unjustifiably block or restrict industrial development in Canada.

Opposition Procedures

A major concern with any issued patent is its validity. No matter how good a patent system is, the CIPO examination is always only between the CIPO and the applicant. However, patents can affect third-party rights, and there is a public interest in ensuring that such patents are granted with the proper scope and that they do not have unduly broad claims.

There is an advantage to creating a system in the CIPO that provides for a challenge by a third party to the validity of a patent, short of a full-blown Federal Court action. Such a system is already in place in Europe and provides for an opposition to be filed to an issued patent within a short time (nine months in Europe) after grant. Such a system allows for a more thorough examination of those few patents that are thought to have strong commercial significance and allows the patent office to reconsider its decision in light of the arguments of third parties. However, we do not wish Canadian opposition procedures to provide for significant delays, and we would like to ensure that the opposition time limit is no longer than six months and that equally tight time frames be used throughout. The example below illustrates a lost commercialization opportunity due to the granting of an unduly broad patent that might have been restricted to claims of proper scope if an effective opposition procedure had been available.

Photo: National Research Council

"Government can act to instill public confidence in biotechnology through a sound patenting policy, an efficient regulatory review process, and by acting as facilitator of a balanced dialogue regarding the impact of biotechnology on Canadian health care, the economy and the environment."

Robert Heft

Patent Scope — A Comparison Of Trading Partners

A multinational pharmaceutical company filed patents in the United States, Europe and Canada relating to synthetic genes that produce Epidermal Growth Factor (EGF) with applications in the treatment of ulcers and promotion of wound healing. The issued patents varied significantly in scope. The narrowest patent was granted in the United States for a specific sequence in a specific vector (known as a plasmid). The European patent was somewhat broader in that it was granted for a specific sequence. Finally, the Canadian patent was issued and was considerably broader in that it claimed any synthetic EGF gene and the EGF produced from it.

The granting of this broad patent to a multinational company effectively prevented a Canadian biopharmaceutical company from commercializing EGF in Canada. ■

A Comparison Of International Patent Examination Systems

Scenario

Inventors are the first to synthesize a gene that occurs naturally and produce urogastrone (Epidermal Growth Factor (EGF))

Patents Granted

United States Patent 4,719,180
"The plasmid pUrl" — *specific sequence in specific vector*

European Patent 46,039
"A synthetic gene characterized in that it codes for the expression of urogastrone ... in a bacterial cell and comprising the following 159 base sequence" — *specific sequence*

Canadian Patent 1,197,797
"A synthetic gene characterized in that it codes for the expression of urogastrone or a sub-unit thereof" — *EVERY possible sequence*

Result

A Canadian biopharmaceutical company abandons plans to commercialize EGF because a multinational company is awarded a broader patent in Canada than in other jurisdictions. ■

The Practical Importance of an Effective Opposition System

Issuance of broad patents, especially when these patents are broader than those granted by our trading partners, can hamper the commercial activities of Canadian companies. As shown in the example above, the result was that the Canadian company did not pursue the commercialization of EGF in Canada but subsequently licensed its EGF technology to a pharmaceutical company based in Southeast Asia. An effective opposition process would have provided an opportunity to restrict the scope of the Canadian claims to be similar to those in the United States.

Recommendation

NBAC recommends that the Canadian Intellectual Property Office introduce an effective opposition procedure with a time limit of six months after grant, similar to procedures in Europe.

4.3.3 Fast-tracking

Additionally, refinements to the examination system, such as fast-tracking claims that are identical to those approved in other jurisdictions, can result in resources being devoted to ensuring that quality patent examination occurs when it counts most. It is important for Canadian industry that the Canadian patent office issues only patents of a scope justified by the invention made and consistent with the scope of patents granted by Canada's major trading partners.

Canadian patents that are the same as patents granted by Canada's major trading partners are rarely serious economic impediments, particularly since a Canadian company selling worldwide must avoid the broadest claim in force in its trading area. However, it can be a serious problem if Canadian patents are issued with coverage significantly broader than the patents issued by our trading partners. This can happen if the patent office has insufficient resources to devote to proper examination of new patents.

Recommendation

NBAC recommends that the federal government implement a fast-tracking system for patents filed in Canada that have identical claims to patents already issued in the United States and Europe. The Canadian Intellectual Property Office should allocate additional resources to the examination of patents thought to be too broad or controversial in their claims.

Therefore, scarce resources should be allocated to those cases in which broader claims are sought. If the government allowed an applicant to bypass (or fast-track) substantive examination when the claims conform to an issued case in the United States or Europe, then greater resources could be devoted to cases in which significantly different coverage was sought in Canada. Such a system apparently works well in Australia.

4.4 Regulatory Efficiency and Competitiveness

4.4.1 Benchmarking Approval Times

Canada's regulatory framework for biotechnology is built on the existing regulatory framework for traditional products and processes. This system emphasizes product safety and efficacy. It is clear that in some product areas, such as agriculture, the efficiency of the Canadian regulatory system is superior to that of its international trading partners. For example, Agriculture and Agri-Food Canada (AAFC) is sensitive to needs imposed by crop planting timetables — and should be commended for the extra effort expended to ensure that new crop regulatory decisions are given in time for the new planting season. As well, assessment of novel food products by Health Canada takes only 90 to 180 days.[1]

Canada/United States Comparison

Average Drug Approval Times (days)

	1995	1996
Canada	710	531
United States	483	436

Source: FDA Website; *Therapeutic Products Directory* (1996).

In other sectors, however, despite efforts by officials to cut down inordinate delays, Canadian companies can still incur competitive disadvantage vis-à-vis international competitors. In the biopharmaceutical sector Canadian approval times lagged behind those of major trading partners in 1995 but showed significant improvement in 1996.[2]

Recommendation

NBAC recommends that the federal government establish competitive Canadian target time lines for biotechnology product approvals through a process of comprehensive international benchmarking of regulatory approval times, and make this information public.

Expeditious approval times are particularly important since delays can have a significant impact on company profitability. It is estimated that in approving a product, each additional day of delay can cost a company $1 million in lost sales. Canada still lags nearly 100 days behind the U.S. Food and Drug Administration's average time for approving new drugs to market.

A program of benchmarking regulatory approval times against competitors and

1 Information provided by the Office of Food Biotechnology, Health Canada.

2 Information provided by Therapeutic Products Directorate, Health Canada.

making public the comparisons would help to ensure that Canada is closing the performance gaps and that its system of product approvals remains one of the world's best without compromising standards.

4.4.2 A Smart Regulatory System

An advantage for the Canadian system is that the specific requirements for review are put in guidelines to the regulations rather than the regulations themselves. This makes it easier for departments to modify them to take into account the particular characteristics and risks associated with different products of biotechnology.

Recommendation

NBAC recommends that the regulatory system ensure officials build on their accumulated experience with the underlying science needed to assess risk, in order to reduce unnecessary information demands on industry. An annual assessment should be submitted to Treasury Board.

The system is not, however, making adequate use of accumulated experience. Data requirements have not been changed to take into account accumulated departmental experience with the products. Departments regulating the products of biotechnology should be required to report annually to Treasury Board through their minister indicating how the regulatory burden has been reduced through accumulated experience. There is also a need to ensure that the information requirements for the approval process reflect specific concerns about the product.

4.4.3 Use of External Advisory Panels

Timely regulatory decision making is needed to support innovation. Expertise is required to handle new challenges expeditiously without compromising the quality of product reviews. As biotechnology rapidly advances, regulating departments can no longer expect to contain in-house, or even in the country, all the expertise necessary for assessments. The increasing number and complexity of commercial products of biotechnology will place growing strains on regulatory authorities to either augment the number of product assessors within departments or have products evaluated utilizing external assessment as a cost-effective tool for streamlining services. As national budgets become more constrained, the practice of external assessment should be encouraged to ensure efficiency in the system.

4.4.4 Bio-farming: A Regulatory Conundrum

At hand in some jurisdictions are new classes of products that pose a fresh challenge to the regulatory framework. One of these, for example, is a variety of corn genetically engineered to produce antibodies for use in human medicine. In the current regulatory framework, such a corn variety might be considered to be, simultaneously, a crop, a feed, a food and a drug. With increasing frequency, multifunctional products such as these will pose a challenge to the capacity of the regulatory system to coordinate approvals within and between departments.

Recommendation

NBAC recommends that a streamlined, flexible and cooperative approach to regulatory approval of multifunctional novel foods and drugs meeting health and safety standards be developed immediately by all relevant regulating departments.

Biotechnology is extremely dynamic. Capabilities are advancing rapidly, posing new regulatory challenges. The advent of bio-farming, and the need in many cases to extract the value-added component from the plant and purify it (often to a high degree) will introduce new stresses and strains into the bio-agriculture system. These challenges will be not just for the companies developing the new varieties, growing them, processing and purifying the end products, but also for the Canadian agricultural, environmental and health regulatory systems. Regulations and approval systems must be prepared for these new challenges.

Given the substantial cost of regulatory delay, many companies would be prepared to pay the cost of expedited regulatory product review. The fees collected could be used to hire additional personnel to make the system more expeditious in general. For situations in which Canada lags badly, owing to a lack of resources, NBAC has identified the following strategies to reduce the time lag.

Photo: National Research Council

Recommendation

NBAC recommends 1) that departments or special operating agencies regulating biotechnology establish external advisory panels composed of experts in the particular biosciences required to improve the regulators' capability to deal with the increasing number of products of biotechnology moving into commercialization, 2) that the expedited approval process currently in place be expanded and used in parallel with the regular system, and 3) that fees collected be reinvested in the regular approval system to make it more efficient.

4.4.5 Regulation of Naturally Occurring Organisms

The *Canadian Environmental Protection Act* (CEPA) regulates the production and import of organisms, in particular naturally occurring micro-organisms. Before any such organism can be imported or manufactured in Canada, it must receive approval through a prior notification process if it is not listed on the Domestic Substances List. This presents a particular problem to Canada since the Domestic Substances List, under CEPA, has relatively few organisms on it. For organisms not listed, and therefore considered novel, full regulatory data packages must be produced.

In contrast, the U.S. Environmental Protection Agency had the option of covering either naturally occurring or genetically engineered organisms or both under the *Toxic Substances Act*. It chose to require notification only for the genetically engineered organisms. Therefore, no approval procedure is required in the United States for the manufacture of any indigenous naturally occurring organism. Furthermore, the United States declared the whole of North America, including Canada, as one eco-zone.

In Canada, however, if a company isolates a naturally occurring organism and decides to grow the organism for commercial use, it must notify AAFC or Environment Canada and proceed through an extensive notification and environmental assessment process, even if the organism is only being manufactured for export. Additionally, the company must make a separate notification for each of the 15 eco-zones in Canada.

Canadian regulations thus impede research into natural bioremediation products. Companies researching such products face costs between $60,000 and $100,000 just to notify the government that they are doing so. This presents a disincentive to research and development of these naturally occurring substances and places Canadian bioremediation companies at a significant competitive disadvantage in international markets.

Recommendation

NBAC recommends that the federal government ensure its regulations are equivalent to those of Canada's trading partners and that they do not put Canadian companies at a disadvantage when researching and/or bringing forward new products based on naturally occurring micro-organisms.

4.4.6 Regulatory Challenges Encountered at the Level of Provincial Formularies

The power of the provinces over provincial formularies has become an additional regulatory hurdle in the Canadian system — equivalent to another round of product approval procedures for biopharma products. No one contests the right of the provinces to regulate in these areas. But the federal government must accept some responsibility for the functioning of the system as a whole. In particular, the federal government should work to ensure the development of common data requirements and mutual recognition procedures.

Recommendation

NBAC recommends that the federal government work with the provinces to ensure that the provincial power to regulate formularies does not become another barrier to trans-Canada trade in biopharmaceuticals.

4.5 Regulation and Public Confidence

Canada's health and safety and environmental regulations have evolved over a century to become among the world's best. Based upon solid science-based risk assessment, Canada's comprehensive procedures have the potential to be a competitive advantage for biotechnology commercialization. The label "Approved in Canada" could become internationally synonymous for safety. However, to develop such a profile, our system of health and safety regulations needs to be communicated to the public much more effectively. It is one of our strategic competitive advantages.

The existing regulatory framework must be transparent so that producers and consumers understand the regulatory process and the formulation of regulations. Interest groups need also to be assured that their views are being considered during the formulation of new regulations.

To generate public confidence and trust requires not only a system that operates effectively but also one that commands public support because stakeholders views have been heard and stakeholders recognize their priorities have been considered in the process as it is implemented. Building public trust requires that mechanisms are in place to obtain public input and that inputs are subsequently appropriately considered in policy formulation. It also requires that government speak clearly, with a unified voice, and stand firmly behind the decisions of its regulatory system. These regulatory

decisions must also be communicated in non-specialist's language so that they can be clearly understood by members of the public.

In developing regulations, the Canadian federal system follows a written notice and public comment procedure. In this procedure, each new regulatory proposal must pass through a Regulatory Impact Assessment Statement (RIAS) and stakeholder input must be solicited before promulgation (i.e. published in *Canada Gazette* Part II). In other words, regulators have to consult the stakeholders when they change the rules, and report on the consultation procedures they undertake in developing new rules (see box below).

Regulatory Impact Analysis Statement (RIAS) and Regulatory Process Management Standards (RPMS)

The RIAS must describe the regulatory proposal, how Canadians have been consulted, the benefits and costs of the proposals, and other alternatives considered. The requirement to publish an RIAS in effect establishes the framework for consultation with concerned publics during the process of developing new regulations.

In addition to the RIAS, Canada's regulators must also conform to RPMS set out by Treasury Board. These guidelines are designed to ensure that regulatory decisions are implemented in a timely, effective and fair manner.

Nevertheless, there are only limited formal mechanisms that standardize the collection and incorporation of public input for a proposed measure. The real challenge is for government to reach out beyond the specialized audience of the *Canada Gazette*. Government communications with the public and industry must become more helpful and effective and, in particular, new communications pathways need to be established. Here are some suggestions to indicate the kind of steps that should be considered.

Recommendation

NBAC recommends that 1) consistent and transparent public access routes (including Web sites) be developed for explicitly reporting and analyzing public comment received when proposing legislation and new or modified regulations, thereby closing the feedback loop to the public, and 2) the government release to the public, after taking into account commercial confidentiality agreements, plain-language versions of the regulatory decisions and the rationale supporting those decisions.

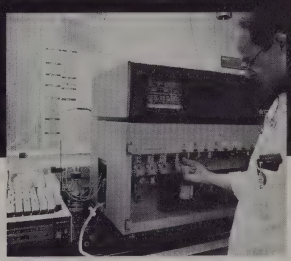

Photo: Allelix Biopharmaceuticals Inc.

"Biotechnology is an enabling technology critical to the development of Canada's knowledge-based economy."

Kelvin Ogilvie

The Socio-ethical Context of Biotechnology

CHAPTER 5

ABSTRACT At the same time that biotechnology presents humankind with unprecedented opportunities to enhance quality of life and contribute to jobs and growth, some applications raise profound social and ethical questions. The need for public dialogue on the broad implications and consequences of biotechnology is urgent. So also is the need for the development of new public policy tools to systematically incorporate socio-ethical considerations.

This chapter examines international best practices for assessing socio-ethical issues, facilitating public input and analysis, fostering public awareness and public confidence, and providing advice to the government on biotechnology.

The report puts forward recommendations for revisions to the mandate and structure of the government's current advisory body. The Report proposes a renewed advisory council with an expanded mandate that would also include examination of socio-ethical issues and a public role to facilitate a broader national dialogue in order to enhance public awareness and understanding and ensure increased public participation.

"These issues are not matters for a single day, deserving of occasional attention. They will be of concern... for the foreseeable future. Indeed, the results of research and development in gene splicing will be one of the major determinants of the shape of that future. Thus, it is important that this field, with its profound social and ethical consequences, retain a place at the very center of the conversation of [humankind]."

Source: *Splicing Life: The Social and Ethical Issues of Genetic Engineering with Human Beings*, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Washington D.C., U.S. Government Printing Office, 1992.

5.0 Introduction

In February 1997, the world was electrified by the announcement that a sheep named Dolly had been cloned in Edinburgh, Scotland. Newspapers around the world heralded the event as visible proof of the astounding power of biotechnology, with its unparalleled possibilities for economic and quality of life advantages, and the equally challenging array of social and ethical questions.

As Canadian biotechnology-based industries move successfully through the commercialization phase, it is important that decision makers facilitate public dialogue and elaborate public policy instruments for systematically incorporating socio-ethical considerations into decision making.

Managing this technology ethically requires a commitment to public participation in the policy process. It is fundamental to fostering public understanding and public confidence.

A number of products of biotechnology are in the market and have been in use for some time. Diabetics have been using genetically engineered human insulin for a number of years. Canola, one of the more successful Canadian agricultural products and one that has been bred to provide extremely high quality vegetable oil, has also enjoyed considerable market success. Potatoes, genetically modified for pest resistance, have been successfully test-marketed in Atlantic Canada recently.

Photo: StressGen Biotechnologies Corp.

Commercialization of these products has enjoyed considerable consumer acceptance. These successes show that Canada's regulatory system is working well to ensure the health and safety of products of biotechnology. Some applications of biotechnology, however, have raised specific social and ethical issues in society that the regulatory process is not designed to address. As the number of these novel products increases in the marketplace, interest groups and the public will want to ensure that their concerns are heard and addressed, that values are clarified, and that best practices are established to manage the manifold potentials of this technology in a socially responsible way. Achieving these goals will require new mechanisms.

As a basis for establishing the nature of these mechanisms, three areas should be examined: 1) the nature of public perception of biotechnology applications, 2) the larger social context for the introduction of biotechnology products into the marketplace, and 3) the mechanisms that have been employed as best practices in other countries to ethically manage this technology.

Comparative Public Opinions: "% who want to encourage biotechnology applications"

	Canada	U.S.	U.K.	France	Germany	Italy
Using biotechnology in production of food and beverages	60	57	45	39	41	47
Inserting genes into crop plants for pest resistance	77	65	59	57	50	70
Inserting genes into bacteria for new vaccine development	85	81	75	76	67	73
Developing genetically modified mice for cancer studies	71	n/a	38	52	31	51
Using genetically modified animals to produce organs for human transplant	57	43	35	43	32	41
Using genetic tests on embryos to check for genetic diseases	74	71	80	83	64	83

Based on: E.F. Einsiedel, *Biotechnology and the Canadian Public: Report on a 1997 Survey, and Some International Comparisons*, Report to the Social Sciences and Humanities Research Council, University of Calgary, September 1997; and J.D. Miller, "Biotechnology and the American Public," Unpublished Report, Chicago Academy of Sciences, February 1998.

5.1 What Canadians Think About Biotechnology

Public perceptions about biotechnology have been investigated on numerous occasions, both in Canada and internationally.[1] The table above summarizes comparative public opinions regarding biotechnology applications.

Clearly, judgements about biotechnology are heavily influenced by the social goals it serves, the processes employed in the application, and consumers' values and experiences. For instance, human medical applications enjoy high levels of support, while enhancing food quality has relatively less support. Additionally, some anxieties are evident for certain types of gene transfers. Perceptions of moral acceptability, risk and utility also shape product acceptance.[2]

Finally, consumer attitudes are shaped by their experience with other modern technologies, their trust in regulatory institutions, their trust in industry and their fundamental beliefs about the relationship between nature, science and humankind.

Trust in industry and government becomes critical to consumer acceptance of advanced technologies when personal control is limited, information is complex and perceived changes may be dramatic. The issue of trust is especially important when consumers do not have much information about particular products, or when there is scientific uncertainty about these products (such as their long-term effects). This leads to a heightened sense among consumers that they have little or no control over technology. In this situation, institutional trust becomes critical.

1 Decima Research. *Public Attitudes Toward Genetic Engineering.* Report to the Canadian Institute of Biotechnology. Ottawa, 1993. Optima Research, *Understanding the Consumer Interest in the New Biotechnology Industry.* Report to Industry Canada Office of Consumer Affairs. Ottawa, 1994. Einsiedel, E.F., *Biotechnology and the Canadian Public: Report on a 1997 Survey and Some International Comparisons.* Report to the Social Sciences and Humanities Research Council and the Canadian Institute of Biotechnology. Calgary: University of Calgary, 1997. See also Biotechnology and the European Public Concerted Action Group, Europe ambivalent about biotechnology. *Nature*, 387, 26. June 1997, 845- 847.

2 Einsiedel, E.F., 1997. *Biotechnology and the Canadian public: Report on a 1997 Survey and Some International Comparisons*

Potential Policy Questions

Human Tissue Questions
What norms should be applied to the procurement, storage, accessibility and use of human tissue, cell lines and similar human biological materials for research or cultivation as biotechnology agents?

Labelling
Should all genetically modified food products be labelled as such?

Transgenic Organisms
For what ends should we create transgenic animals?

Biodiversity
What are the implications of certain biotechnology applications on biodiversity?

Protection of the Vulnerable
Which social groups face risks of being discriminated against based on genetic information and how should they be protected?[3] ■

Segments of the biotechnology industry engaged in product distribution and consumer sales are particularly sensitive to consumer responses. Some have commissioned studies investigating which issues consumers are most concerned about when they receive messages about biotechnology products.

Issues of Credibility

A consumer study of public communication and novel foods, sponsored by the Food and Consumer Products Manufacturers of Canada, concluded that, more than credentials, consumers want reassurance about the character of the firms with which they do business and the people who represent them. The survey included the following questions: Are you an ethical person? Do you care? Are you honest? Do you have respect for the laws of nature? Do you understand risks? Can I trust you?

Source: L. Curry, *Communicating to Canadians about Novel Foods*. Presentation to Biotechnology and the Consumer Conference, Industry Canada Office of Consumer Affairs, Ottawa, September, 1997.

5.2

The Social Context of Opinion Formation

The production, diffusion, and adoption or rejection of biotechnology products do not occur in a vacuum. Consumers consider social and ethical commitments in their purchasing decisions (e.g. green products).

In considering the social context within which opinions and purchasing decisions about biotechnological applications develop, two factors are important to understand: 1) the decline of the public trust in institutions and consequently the demand for participation and transparent mechanisms for dealing with social and ethical aspects of technology, and 2) the need for explicit recognition and discussion of the ethical dimensions of a number of biotechnological products or services.

3 Derek Jones, *Ethics and Biotechnology: The Role of the Government of Canada*. Presented to the Federal Interdepartmental Working Group on Ethics. June 1997. See also Ted Schrecker and Margaret Somerville, *Making Ethically Acceptable Policy Decisions: Challenges facing the Federal Government*. Report to the Federal Interdepartmental Working Group on Ethics, May 1997.

Today's Citizen-consumer

Canadians are less inclined to accord authority over issues to government or other institutions. Today's citizen-consumer wants more say in government decision making and more transparency in institutional procedures.

While the public still believes science and technology offer a credible promise of a better quality of life and higher living standards, the public is also mindful that mistakes can and have occurred, sometimes with disastrous consequences. Whenever possible, members of the public would like some reassurance that their interests as citizens and consumers are being considered and, more importantly, can be expressed.

The Ethical Dimension

While there is clear public support for biotechnology, there remain some serious ethical questions related to specific applications. These concerns need to be confronted, understood, discussed and considered in decision making.

The US President's Commission on Biomedical Issues called for a continuing societal "conversation" on the social and ethical issues of genetic engineering in human beings. Among a range of questions requiring reflection and public input could be those set out on the previous page in the box on potential policy questions, among others.

Mechanisms of Public Involvement in Biotechnology

Approach	Representativeness	Quality of Info	Feasibility	Advantages	Disadvantages
Notification, distribution, solicitation	**	**	***	Simple methodology; comments detailed	Limited participation
Public opinion	****	*	***	Accessible; overall picture possible	Limited explanation; unidirectional
Focus groups	*	***	***	Good process for exploring opinions	Limited participation
Consensus conferences	**	***	**	Dynamic participation; lay-expert interaction; process transparent; informed opinion	Number of participants limited
Sequential consultation	**	***	**	Verification, clarification of positions	Participation limited to interest group leaders
The Internet	*	***	***	Quick responses; detailed input possible; interactive	Access and skills not widespread
Referenda	**	*	*	Direct democracy; direct policy input	Very expensive; dependent on quality of information available; decision impacts may be questionable; not necessarily informed opinion

Legend: * Poor **** Very Good

Source: Adapted from Therese Leroux, *Comparative Study of Mechanisms Developed in Other Countries for Reviewing Ethical and Social Issues of Biotechnology*. Report to Office of Consumer Affairs, Industry Canada, September 1997.

5.3
What Can We Learn from Other Countries' Experiences?

Public participation has been encouraged from the early 1980s in the United States and Europe through a range of mechanisms. These include community dialogues and workshops, consensus conferences and stakeholder consultations. There is no one right approach to public involvement. Each approach has its own set of strengths and weaknesses.

In the United States, the Ethical, Legal and Social Implications (ELSI) program of the National Institutes of Health's Human Genome Project sponsors public opinion research as well as projects for more direct public participation.

The National Institutes of Health budget allocated to understanding and incorporating public opinion is US$1.5 million annually.

Many other countries have deemed public involvement to be a critical element in the management of the biotechnology policy process.

In Europe, a strong tradition of public participation mechanisms exists. Many mechanisms have been utilized in policy considerations on biotechnology, with Denmark and the Netherlands at the forefront. Dialogue workshops have been held in local communities so that small groups may learn about technology and have the opportunity to ask questions of experts. In Germany, public awareness and consultation activities have been conducted by Centres of Technology Assessment supported by a number of state governments.

The consensus conference is another institutional mechanism developed in Denmark and adopted in the Netherlands, the United Kingdom, Norway and Austria. It brings together a lay panel and a panel of experts. The lay panel has the opportunity to learn about a specific technological application and to question experts regarding the scientific, social and ethical implications of such applications. The panel then writes a report that provides another input into the policy process. Much more formally, in countries such as Switzerland and Austria, a referendum process provides an even more powerful mechanism for public control of policy decisions.

Advisory committees or panels **are another mechanism for examining larger social questions about biotechnology.** These bodies have the advantage that they can 1) provide expert advisory opinions to government on ethical matters, 2) stimulate and channel public and government debate and reflection, 3) help build consensus towards a broad ethical framework and like norms that help to define socially acceptable policy positions and 4) inform public policy, regulation and law.[4]

The advisory structures in the United Kingdom offer good examples of the performance of these roles. There are seven or eight advisory committees, each dealing with a particular dimension of biotechnology. For example, an Advisory Committee on Releases to the Environment (ACRE) deals precisely with issues indicated in its name. Another, The Human Genetics Advisory Commission (HGAC) set up in 1996 has the mandate "to keep under review scientific progress at the frontiers of human genetics and related fields and to report on issues arising from new developments in human genetics that can be expected to have wider social, ethical and economic consequences".

4 D. Jones, 1997, Ibid.

HGAC is currently examining three social issues in the U.K.: life insurance and genetic testing, the social implications of genetics, and public consultations on developments of cloning. It is performing precisely the anticipatory social role that advisory structures are designed to perform. After reviewing an issue, the HGAC puts together a discussion document written in lay language and, after obtaining public input, rewrites the document for public dissemination. This commission operates on principles of transparency and public accountability.[5]

Perhaps the most energetic public communicator is the Danish Council of Ethics (DCE). The DCE produces a teaching package and teachers' guides on "Genes as Medicine," and publishes conference reports on proceedings and conclusions from discussions of specific issue areas. It also facilitates Debate Days for the public, always publicizing these events before and as they occur. It has an active Web site where it publishes and disseminates statements submitted by the Committee on the social issues arising from biotechnology research and applications. The DCE also replies by phone and in writing to enquiries from the general public. These public communication activities have become sufficiently important in scope and frequency that, in 1995, the Council set up an information group to coordinate the Council's information activities and to evaluate the success or failure of these programs.

The European Commission has set up the European Group of Advisors on the Ethical Implications of Biotechnology. This organization has established a number of working groups. To date, they have examined several areas of biotechnology that raise public concern, such as intellectual property rights and genetic therapy, biotechnology-derived foods, prenatal diagnosis, and the genetic modification of animals.

The U.S. National Bioethics Advisory Commission reports directly to the National Science and Technology Council, federal agencies and the President. All its reports are made available to the public. The Commission considers matters that involve genetic information, including patenting and privacy issues. It also considers suggestions made by the public as well as those of government agencies, and has the power to initiate issues for consideration. Membership includes scientists, theologians, ethicists, lawyers and lay people, with special attention to the representation of minorities so that a wide variety of social perspectives may be heard.

On the multilateral level, over 150 UNESCO member countries participate directly or indirectly in the work of the International Bioethics Committee (IBC).

The Universal Declaration on the Human Genome and Human Rights, initially drafted by the IBC and reviewed by the International Bar Association, was adopted by consensus at the UNESCO General Council in the fall of 1997.

The Human Genome Organization (HUGO) is an international organization of scientists involved in the Human Genome Project, the global initiative to map and sequence the human genome. HUGO has undertaken to direct up to seven per cent of its budget to its Ethical, Legal and Social Implications Committee, which is currently chaired by a Canadian.

5 Human Genetics Advisory Committee, Office of Science and Technology, March 1997.

Industry Initiatives to Develop Ethical Guidelines

Industry has an important role to play in public discussions on the social and ethical dimensions of biotechnology. Socially responsible management means that commercial concerns cannot be divorced from socio-ethical considerations. **The Industrial Biotechnology Association of Canada (IBAC) now has an ethics committee and has begun the process of examining broader ethical issues. BIO, the industry organization in the United States is also concerned with ethical issues**. For example, BIO has publicly supported efforts to create federal standards to protect confidentiality of an individual's medical information, including results of genetic testing.[6]

Individual companies may also find it helpful to establish their own bioethics advisory committees as their products approach the market. For example, in December 1997, Bayer Inc. of Canada announced the formation of an Advisory Council in Bioethics comprising eight leading bioethics experts, technical experts and community members to examine issues pertaining to blood products. Bayer is the largest supplier of plasma fractionation products to Canada.

The implementation of voluntary codes provides another mechanism for self-regulation and for adherence to social and ethical performance standards. This proactive position is illustrated by the Responsible Care® program of the Canadian chemical industry. The program's objectives are to improve industry performance, improve relations with government and foster increased public trust. It is a self-regulatory program in which industry members commit to following six codes of practice covering every step in a chemical's life cycle, from research and development to ultimate disposal. Companies have three years to fulfill the obligations after agreeing to comply with the program, after which they are subject to a performance evaluation. If successful, they receive the industry's official certification. **A National Advisory Panel consisting of concerned citizens, environmental activists and consumer advocates, academics, and experts oversees the program and provides advice on its further development and implementation**. The overall aim has been frank and open discussion between industry and the public on issues of mutual concern.[7]

Many of the issues posed by biotechnology are new and unprecedented, making the adoption of a voluntary code more challenging for the biotechnology industry. Other factors further contribute to this challenging task. For example, these codes have been found to be most workable for mature and stable industries, for industries that are relatively similar in size, when there is leadership from key industry players, when there is a strong industry association, or when there is pressure from the public or government.[8] The biotechnology industry in Canada does not currently share some of these characteristics. Given the potentially controversial issues that surround biotechnology (including privacy, selected environmental impacts or genetic engineering in general) a proactive stance by industry on a voluntary code may be significant and beneficial in the long run.

NBAC commends IBAC for having established an ethics committee with the mandate to develop an industry code of conduct and subsequent code of ethics, and recommends that these initiatives be further expanded to include steps necessary for the industry to adhere to these codes. ■

6 BIO Policy Statement Regarding Genetic Privacy, Sept. 18, 1996.

7 Canadian Chemical Producers Association, Responsible Care® Program, 1997.

8 "Voluntary Codes and the Consumer Interest," *Consumer Quarterly*, Office of Consumer Affairs, Industry Canada, 1:4, October 1996.

5.4 Canada's Mechanisms for Public Involvement in Biotechnology

Canada has both governmental and non-governmental structures providing socio-ethical policy guidelines. For example, Research Ethics Boards (REBs) help to oversee the conduct of publicly funded research, including biotechnology research, that involves humans or animals. All such research must undergo ethical review. Research ethics boards are used by hospitals, universities and government granting agencies.

Currently, national ethical guidelines related to research on humans are being revised. New ethical guidelines are expected to be finalized in early 1998 by the Tri-Council Body representing Canada's Medical Research Council, the Natural Sciences and Engineering Research Council, and Social Sciences and Humanities Research Council.

Until early in 1997, the Canadian Genome Analysis and Technology Project (CGAT), funded by MRC, Industry Canada and the National Cancer Institute of Canada, allocated seven per cent of its funding to its Medical, Ethical, Legal and Social Implications (MELSI) subcommittee. (During the implementation of the CGAT, 12 per cent of the $22 million was eventually spent on MELSI research.) The purpose of the MELSI component of the CGAT program was to address and anticipate the medical, ethical, legal and social implications of human genome research and its related applications in society.

Canada's Social Sciences and Humanities Research Council (SSHRC) has championed research in this field. The funding available through the MELSI element of CGAT has been a significant factor in the ability of Canada to lead the world on MELSI issues. While CGAT funding for research has now been reduced to $1 million, there is now no funding for MELSI-related issues. It is vitally important to reinstate support to sustain momentum in this capacity and build on Canada's internationally recognized leadership in MELSI issues (see recommendation, Chapter 3).

Canadian stakeholder groups have themselves been carrying out a range of public awareness activities, all of them with some government support. The Canadian Institute of Biotechnology (CIB), supported by Industry Canada, has been involved in a number of these activities, with particular emphasis on educational efforts in the schools. A fledgling Food Biotechnology Communications Network, with members from various private, public, and non-profit organizations, has held a variety of public workshops. Organizations representing consumer and environmental groups have similarly engaged in public awareness efforts among their members. Various government agencies have conducted a broad range of public surveys and consultation efforts with stakeholders. As well, initiatives at the provincial level have taken place through provincial or regional biotechnology networks or alliances. Yet there is no apparent overall coordination of these efforts and effective exchange of information.

Canada remains one of the few remaining industrial countries lacking a national, publicly accountable advisory body to manage a national dialogue on biotechnology.

While Canada, therefore, has some mechanisms for addressing fairly specific types of biotechnology issues (such as human genome research, specific legislative and regulatory matters, consumer issues and environmental questions), there is no overarching mechanism for holding a non-partisan, national conversation about biotechnology. Nor are there public policy tools for systematically and consistently incorporating socio-ethical considerations into public policy formulation and decision making.

"Biotechnology — a democratic challenge."

"Trust, benefit and control determine the perception of risk. Public participation in the biotechnology decision process and the provision of choices in the marketplace could go a long way to foster a sense of control and build trust. This is where biotechnology is a democratic challenge."

Suzanne Hendricks

5.5 Facilitating Public Dialogue

The federal government has the capacity to play a key role in a public dialogue on biotechnology by facilitating partnerships among various stakeholders at provincial and national levels. But, if the conversation is to be non-political, the government cannot undertake this dialogue directly. Rather, an arm's-length advisory body could provide a publicly visible, accessible and accountable centre for this conversation. Such a body could contribute significantly toward articulating the elements of an ethical framework for decision makers that could guide further national and local discussions on biotechnology and contribute toward policies and regulations that are and are seen to be socially responsive and responsible.

A National Conversation on biotechnology, facilitated by a new advisory body with a broadened mandate, would encourage public involvement in the evolution of this technology and enhance public confidence in Canada's capacity to manage biotechnology with a socio-ethical framework that reflects Canadian values.

Recommendation

NBAC recommends that it evolve into an advisory body with a public role and a broader membership and mandate to include, in addition to its current terms of reference, the consideration of a socio-ethical framework for biotechnology policy.

NBAC recommends that the broadened advisory body catalyze a National Conversation on biotechnology to ensure the systematic and consistent incorporation of public input on the socio-ethical dimension of biotechnology policy formulation.

A Renewed National Biotechnology Advisory Structure

CHAPTER 6

ABSTRACT The rapid introduction of products of biotechnology to the marketplace in the 1990s raises issues that the current NBAC mandate does not address. Two such elements are the addition of a socio-ethical dimension and the inclusion of a public role in its mandate. Extending the mandate in this way would require that NBAC membership be broadened to ensure a wide ranging set of expertise in areas such as socio-ethics, equity, health, safety and the environment, public communications, education, industry, research and youth. Ministers and officials from all departments with biotechnology responsibilities may from time to time participate in meetings of a new advisory body. The renewed Committee, reconstituted as a council would require a dedicated annual budget and a small secretariat for outreach purposes to complement its continuing advisory role to ministers, to support its public role, and to coordinate working groups on special issues. The Information Highway Advisory Council is seen as a Canadian model.

6.0

Rationale for Renewal: Public Involvement and Socio-ethical Considerations

The National Biotechnology Advisory Committee (NBAC) was established under the National Biotechnology Strategy (NBS) elaborated in 1983. Its original mandate was developed when the industry was at the earliest stages of its formation in Canada. The mandate called for the NBAC to monitor international, federal and provincial initiatives, and directed it to advise the Minister of Industry on the evolution of Canada's science and technology infrastructure and the government policies and programs related to biotechnology. It was originally designed to focus more on the science than on the market. Now that the field has moved from scientific discoveries in the laboratory to the early stages of commercialization, there are more public issues to be considered. Transparent and enhanced communications, both within government and between government and the public, are now required.

The current NBAC recognizes that an advisory body to government must move beyond giving advice on the scientific, economic and regulatory aspects of biotechnology's development. A council with a new mandate should provide a framework for public communications, awareness and input. The new advisory structure should also provide recommendations on the public policy steps needed for the incorporation of socio-ethical considerations into decision making. These steps will foster public participation and enhance public confidence in how biotechnology is used in Canadian society. Building such public support and confidence requires a broader base of experience and perspective, and significantly more resources than NBAC now enjoys.

The new national advisory council should be more inclusive, able to listen and respond to concerns of Canadians, consult with them on specific issues, and integrate public input into its advice on socio-ethical guidelines for decision making and a policy framework.

In today's fast-paced competitive world, the citizen-consumer rules. To achieve successful commercialization and meet the goals in the recommendations of this report, Canada's biotechnology industries must generate broad public support. As increasing numbers of biotechnology health and novel food products enter the marketplace, one thing is certain: consumer opinions on the socio-ethical issues surrounding applications of biotechnology must be gathered, considered and reflected in the recommendations of the renewed advisory body.

Such a dialogue is already underway in almost all of Canada's major trading partners and at the international level in such multilateral organizations as UNESCO. A national dialogue should open discussion on what biotechnology is, what it can potentially do for the country economically and for our quality of life, its socio-ethical dimensions, and the risks and uncertainties involved in its use. The dialogue could also address the steps for involvement of the public at large in discussing the development, regulation and use of biotechnology.

To underpin such a process, the public must be invited to engage in a National Conversation on biotechnology. The conversation should occur outside the political process, and it should be an opportunity for a frank, national exchange.

A successful model of this was mounted for the International 1997 Global Knowledge Conference (GK'97) by the World Bank and Canadian International Development Agency (CIDA). This conference mounted an international interactive electronic dialogue that preceded the conference and continued following the event.

The role of the council members would be to stimulate the conversation in their home regions and, with the help of the secretariat, ensure that findings were disseminated and resources, such as expert speakers and factual information about biotechnology, would be available. The National Conversation would not aim to determine particular policy outcomes. Policy advocates would however, no doubt dip into the conversation from time to time to test their views. The role of the council would be to keep the conversation open, ongoing and well supplied with relevant scientific information.

Central to the goals of such a conversation would be the development of a socio-ethical framework for public policy decision making with the objective to clarify values and help decision makers address specific issues as they arise.

The outcome will be a partnership among the biotechnology industry, governments (federal and provincial) and the Canadian public to enhance Canada's position as a responsible leader in biotechnology.

The NBAC mandate and membership need to be refined so that NBAC, as modified, can continue to play an effective role. The current NBAC is ready to support a transition strategy to reformulate NBAC as a Canadian Biotechnology Advisory Council (rather than a committee) and move into a new structure within 12–18 months, as the new Canadian Biotechnology Strategy is implemented.

Recommendation

NBAC recommends that its current mandate be expanded to include a socio-ethical dimension and a public role and that the new NBAC follow the Information Highway Advisory Council model in operation.

6.1 The New Canadian Biotechnology Advisory Council

6.1.1 Mandate

NBAC considers that its current mandate remains relevant, but proposes that it be expanded to accommodate socio-ethical aspects and a role in facilitating public dialogue and input into policy formation. It proposes additions to the original NBAC mandate under sections g), h) and i) in the box "Proposed Advisory Council Mandate" (opposite).

Proposed Advisory Council Mandate

The Advisory Council will advise minister(s) on all matters related to the continued development of biotechnology in Canada. In particular, the council will respond to questions posed by ministers and will examine and give advice upon the following:

a) the direction and pace of evolution of biotechnology

b) commercial applications

c) the effectiveness of the Canadian Biotechnology Strategy

d) approaches to biotechnology pursued by other countries

e) provincial initiatives in biotechnology

f) federal initiatives outside those promoted through the Strategy that influence the development of biotechnology in Canada

g) public issues and input into policy

h) public awareness and facilitation of a continuing national conversation on the development of biotechnology in Canada

i) formalized mechanisms to consistently incorporate social, ethical, economic, health and safety and environmental perspectives into decision making. ■

A specific role of the Council would be to elicit public input to the consideration of key policy questions. In preparing major policy recommendations, the Council would issue a preliminary report with proposals and then allow a reasonable time period for public comment. It would subsequently issue a final report incorporating an analysis of the public's comments and their impact upon the final recommendations.

6.1.2 Operations

The new advisory body would keep the same arm's-length independence NBAC now has, but emulate the IHAC in its method of operation. IHAC has successfully demonstrated this new advisory model in two rounds of operation since its formation, following the model in the box below.

The IHAC Model

- **responded to key questions posed by ministers**
- **organized working groups**
- **held press conferences**
- **released periodic reports to the public**
- **sunsetted after a predefined period**

Like IHAC, the new advisory body would function as a forum for questions posed by ministers. It would have the flexibility to strike working groups with stakeholders to examine policy questions and the ability to coordinate public discussion as well as provide private advice to ministers. The proposed advisory structure should serve as a flexible and responsive tool for government capable of timely briefings and commentaries as issues arise. More generally, the Advisory Council would operate as a visible, publicly accountable forum for public discussion of biotechnology's impact on Canadian society.

Photo: Allelix Biopharmaceuticals Inc.

6.1.3 Reporting Relationships

NBAC recognizes that as an enabling technology, the impact of biotechnology can be felt in all sectors of the economy. It therefore follows that biotechnology policy involves many federal departments and initiatives by a number of ministers.

NBAC considers, however, that the strategic nature of biotechnology requires that one "lead minister" serve as a focal point. In this regard, it considers that the Minister of Industry remains the best positioned to undertake coordination.

Industry Canada oversees a portfolio with extensive science, industry and consumer interests. These include the Office of Consumer Affairs (OCA), several federal granting councils for university research including social science research (i.e. NSERC, SSHRC and NRC including IRAP), responsibility for federal coordination of science and technology policy, industry sector policy development, and the Canadian Office of Intellectual Property (CIPO). Industry Canada and the Industry Portfolio Agencies also coordinate important instruments including Technology Partnerships Canada (TPC) and the NCEs (through NSERC).

The new Advisory Council should aim to establish consultations with the Advisory Council on Science and Technology (ACST), chaired by the Minister of Industry, to ensure liaison with the Prime Minister's highest advisory council in science and technology.

Recommendation

NBAC recommends that the new Advisory Council report to the Minister of Industry, who would be the focal point in Cabinet for biotechnology issues.

6.1.4 Council Term and Membership

Biotechnology requires that the policy environment remain as flexible as possible to accommodate inevitable changes. NBAC therefore recommends that the new advisory body have a life span of five years (1998–99 to 2002–03). IHAC operated with a sunset clause that came into effect after two years. Its term was renewed once thereafter. Although IHAC is seen as the best practice model, NBAC considers that more time is required for new members to reach consensus successfully on the complex issues involving biotechnology and therefore recommends a five–year sunset clause for the advisory body on biotechnology.

Membership of the new advisory body would be representative of all stakeholders interested in the development of biotechnology in this country. A council of 21 members is proposed to allow for the active participation of people with sound knowledge and seasoned experience of an appropriate aspect of biotechnology.

Members should be able to reflect the public interest from a variety of backgrounds and have knowledge and experience of biotechnology commercialization and finance, biosciences, social sciences, public communications, education, law and ethics. Members should be eminent in their fields, and selected as much for their consensus-building skills as for their special expertise. They would be expected to serve on a personal basis rather than as a representative of a special interest group. The advisory body should also strive to achieve regional, linguistic, cultural and gender balance. Youth should have a specific place on the Council.

Members would be appointed by biotechnology ministers. NBAC suggests that one way to manage this process would be to have the key departments with biotechnology responsibilities[1] propose candidates. As a group, ministers would review the candidates recommended and make their final selection coordinated by the Minister of Industry. Appointments would be made for a term of 18 months. Half the members of the current NBAC would be retained to provide the Council with continuity and experience in its first term. Members would be eligible for one term renewal.

6.1.5 Chair

The Chair would be mandated to consult frequently with departments, agencies, industry and other stakeholders. The Chair should be prepared to brief ministers and make public statements at short notice as required. This individual would have a demonstrated ability to lead through constructive team work and to act as a spokesperson. In consultation with the Minister of Industry, the Chair should be able to comment without prior deliberation of the Council if necessary. The Chair should be chosen by the Minister of Industry in consultation with key ministerial colleagues with biotechnology responsibilities in their portfolios.

6.1.6 Collaboration Among Biotechnology Ministers

The Minister of Industry would function as the focal point and lead minister for the Advisory Council. Other ministers with responsibility for biotechnology (including, Health Canada, Agriculture and Agri-Food Canada, Natural Resources Canada,

1 Currently, Industry Canada, Health Canada, Agriculture and Agri-Food Canada, Natural Resources Canada, Environment Canada, the Department of Fisheries and Oceans and the Department of Foreign Affairs and International Trade.

Environment Canada, the Department of Fisheries and Oceans and the Department of Foreign Affairs and International Trade) would be invited to actively participate in all advisory body meetings. They would participate freely in discussions, and could propose items for the agenda. Ministers of other federal departments and provinces could be invited to participate in particular meetings or included as observers.

6.1.7 Link to the Canadian Biotechnology Strategy

In 1998, the federal government will put into place the new Canadian Biotechnology Strategy (CBS). The advisory body should have a strategic oversight role in the implementation of the revitalized CBS. The Council should meet annually with the interdepartmental CBS coordinating body to fulfill this role.

Recommendation

NBAC recommends that the Advisory Council meet annually with the interdepartmental coordinating body for the Canadian Biotechnology Strategy to provide oversight of the Strategy's implementation.

6.1.8 Secretariat

Organization

The mandate requires both staff support and financial resources adequate to undertake broadened tasks of the Council. Some of the responsibilities of the Secretariat may include the following:

- moderating the ongoing National Conversation
- undertaking special studies related to biotechnology
- operating public communication programs
- briefing members of the Council and the Chair
- liaison with other science advisory bodies
- organizing specialist workshops and public meetings
- coordinating with the CBS and its activities across government departments and agencies.

Budget and Resources

This new arrangement will require some resources. Until now, NBAC has been financed by Industry Canada from within the Bio-Industries Branch base operating budget. The Branch sets aside approximately $50,000 of its budget annually for this purpose, and provides one support person.

This severely limited resource base contrasts sharply with the financial and personnel support of bodies in other countries. For instance, the Human Genetics Advisory Commission in the United Kingdom has an annual operating budget of $2.4 million annually and is supported by four full-time staff. Originally, the National-Biotechnology Advisory Council in the United States had an annual budget of US$500,000. Its term has been recently renewed and its budget set at US$1.5 million annually (more than C$2 million). This council receives additional support from the Department of Health and Human Services.

Photo: National Research Council

Recommendation

NBAC recommends that the new Advisory Council be supported by a secretariat with a staff of four. The Council would be granted an annual operating budget of $1.5 million for five years as an allocation from within the Canadian Biotechnology Strategy, administered by Industry Canada.

6.1.9 Working Groups and External Activities

The new advisory body would organize and fund working groups that include non-members to address special issues. It would also organize and fund public forums and workshops and issue reports. It would set up special ad hoc committees on particular issues at the request of a stakeholder department. Under any such arrangements, the cost of the work would be borne by the department(s) concerned.

6.2 Conclusion

This NBAC report has identified that building a globally competitive industry depends on a number of strategic factors. Key among them are political leadership, the availability of highly qualified human resources and competitive policies for regulations and intellectual property protection. Also important to a thriving industry is a strong science base, access to capital, public awareness and public input into policy, and consideration of socio-ethical dimensions in a national dialogue.

NBAC places top priority on political championship of biotechnology, the availability of highly qualified human resources, and highly competitive policies on intellectual property protection and regulatory approvals.

These priorities must be accompanied by measures to improve access to capital, a significantly reinforced science and technology base, public awareness and input into policy and consideration of a socio-ethical framework facilitated through a national conversation about biotechnology led by a renewed advisory body.

NBAC calls upon the Minister of Industry to rally the support of Cabinet colleagues for the implementation of the 1998 *Sixth Report*. Considered together, the recommendations of the NBAC *Sixth Report* constitute steps in a coherent strategy to position Canada as a leader in one of the most exciting technologies of the next century. If the challenges are not met Canada's biotechnology potential will remain largely unfulfilled. The choice is ours to make!

If the country seizes the opportunity and builds on its biotechnology strengths as prescribed in this report — Canada can lead in the next millennium!

"Leadership in the area of science and technology is a critical gap! As a nation, we have not put a stake in the ground and declared our objectives in a way that leads activities and policies. I believe we must decide that we will be one of the top six countries in the OECD, and then do what is necessary to get there."

Susan Smith

Photo: National Research Council

Appendices

Appendix 1

List of Recommendations

Chapter 1
Poised for Leadership

1. (1.8)

The National Biotechnology Advisory Committee (NBAC) recommends that the Minister of Industry champion biotechnology, recognizing that the extent to which Canada adopts biotechnology and pursues its application and development will significantly determine the country's future economic status and its role in world affairs.

As a national goal, Canada should adopt a target of capturing 10 per cent ($5 billion) of global sales by the year 2005 of products of biotechnology (forecast to reach $50 billion annually by 2005). In achieving this goal, industry should match its top competitors in the ratios of R&D to revenue and revenue per employee.

While continuing to lead in biopharmaceuticals and agricultural biotechnology, Canada should strengthen significantly its focus on applying biotechnology throughout the resource sectors, including forestry, fisheries and energy, as well as mining and the environment.

Chapter 2
Commercialization: Capturing Value in Canada

1. (2.3)

NBAC recommends that industry, business schools and community colleges work together with the Biotechnology Human Resources Council to design executive development programs, master of business administration courses and certificate programs on managing international biotechnology companies. Specialized material should initially cover international trade, investment and alliance strategies, as well as international regulatory affairs in the areas of agriculture and pharmaceuticals.

2. (2.3)

NBAC recommends that the federal government ease immigration rules that hinder timely recruitment of highly qualified individuals and launch a recruitment drive for highly qualified biotechnology managers, provide work permits to spouses of qualified recruits and work with the Biotechnology Human Resources Council to address urgent human resource issues.

3. (2.3)

NBAC recommends that, in the absence of bringing Canada's marginal income tax rates into line with those of its competitors, the federal government adjust the tax rules to permit companies to provide offsetting tax breaks, such as a two-year tax-advantaged savings plan, for newly recruited highly qualified scientists and managers to encourage them to come to Canada.

4. (2.4.1)

NBAC recommends that the federal government adjust its tax rules to allow emerging[1] public companies to keep the same level of refundable tax credits as private corporations for a period of five years after their initial public offering.

5. (2.4.1)

NBAC recommends that the federal government modify the R&D Tax Credit Program to allow public companies with accrued R&D tax credits to use those credits for specific commercialization activities, such as dedicated licensed manufacturing facilities or approved partnerships.

1 "Emerging" refers to early-stage, precommercial companies that are not yet profitable.

6. (2.4.2)

NBAC recommends that the federal government commission a review of Canadian tax policy as it relates to intellectual property and "know-how" in the formation of international strategic alliances and joint ventures. The goal of the study would be to determine how revisions to the tax system could provide Canada with competitive advantage in the critical area of strategic partnering.

7. (2.4.3)

NBAC recommends that the federal government review its tax treatment of capital costs with a view to making available the same write-off provisions as exist in Ontario.

8. (2.4.4)

NBAC recommends that the federal government support (either through mutual recognition or by setting up a National Securities Commission) the creation of a country-wide set of standards for public offerings and company reporting requirements.

9. (2.4.4)

NBAC recommends that the federal government work with the provinces to modify investment restrictions and encourage Labour-sponsored Venture Capital Funds to function as competitive venture capitalists by allowing them greater room to participate in financing emerging companies both nationally and internationally.

Government should consider allowing Labour-sponsored Venture Capital Funds, which currently are limited in the amount of money they can put towards public (versus private) companies, to invest a small proportion of their capital in early-stage public biotechnology companies.

10. (2.4.4)

NBAC recommends that the funds available for biotechnology under Technology Partnerships Canada be expanded so that it can fund at least 10 major projects a year. The project ceiling capacity of the Industrial Research Assistance Program should be expanded to enable the Program to play a larger role in seed-capital financing of R&D.

11. (2.5)

NBAC recommends that its proposals for improving access to qualified managers and scientists, improving the availability of seed capital and enhancing the role of Labour-sponsored Venture Capital Funds, as well as for granting early access to earned R&D tax credits, also apply to agricultural biotechnology.

12. (2.5)

NBAC recommends that, recognizing that the success of Ag-West Biotech Inc. and the successful clusters of innovative industries in Quebec are the fruits of close cooperation among federal, provincial and municipal governments, industry, and the finance and research communities, this cooperation be adopted across the country as an essential element of a strategy to ensure Canada maximizes its potential in this technology.

13. (2.6)

NBAC recommends that the federal and provincial governments work with the forestry industry to develop an improved incentive structure (e.g. long-term land-leasing contracts and cutting rights) that would encourage it to invest in biotechnology applications.

Chapter 3

Science, Technology and Innovation

1. (3.1)

In further support of the recommendations of the December 1997 Report of the Standing Committee on Finance, NBAC recommends that the federal government reinvest in the budgets of federal granting councils to double the 1993–94 level of support within three years, by 2001, and triple the 1993–94 budget in five years, by 2003. New funding should be directed primarily to molecular sciences.

2. (3.1)

NBAC recommends that the federal government advance postgenomic studies through increased funding to Canada's genome program, with a strong emphasis on functional genomics, bioinformatics, proteomics, domain studies and differential gene expression, including allocation to Medical, Ethical, Legal, and Social Implications (MELSI) research.

3. (3.2.1)

NBAC recommends that technology transfer be strengthened in Canada in the following ways:

- university technology-transfer offices undertaking an international benchmarking exercise and developing a program of global best practices
- university technology-transfer offices developing mechanisms such as standard but flexible formats for licensing and cooperative research and development agreements
- the federal government assisting with a full inventory of networks linking universities, industry, venture capitalists and business experts, in addition to the Canadian Technology Network, with a view to making them more accessible and strategic in focus
- governments assisting smaller universities, which have limited technology-transfer capability, with their patenting and commercialization.

4. (3.2.3)

NBAC recommends that the government encourage more initiatives similar to UMDI, the preferred model, to assist in addressing the financing gap at the post-idea stage. As an additional strategy, government programs, such as those of the Natural Sciences and Engineering Research Council and the Medical Research Council, in partnership with industry, should be encouraged to help researchers prove the potential for commercial application and demonstrate the business case for their discoveries in the "post-idea/pre-company niche."

5. (3.3)

NBAC recommends that municipalities, provinces and the federal government work with other stakeholders across Canada to increase support for mechanisms such as regional clusters, bio-incubator facilities and Networks of Centres of Excellence that function to lever funds for and develop a Canadian industrial base.

6. (3.4)

To encourage entrepreneurs and would-be entrepreneurs to pursue innovative ideas and products, NBAC recommends that Industry Canada do the following:

- develop a "virtual network" to allow like-minded individuals to network and link with successful industry mentors and business/managerial information sources, and provide the platform for an employment/recruitment network that reaches out to expatriate Canadians.

Industry, business schools and colleges should do the following:

- develop undergraduate programs and an apprenticeship/internship program at the postgraduate level to give science students vital business experience.

To address the more urgent short term issue of skills shortage, NBAC recommends that Citizenship and Immigration Canada do the following:

- expedite the fast-track immigration process for biotechnology scientists and technology-transfer specialists.

7. (3.4)

NBAC recommends that industry, government and educators work together to ensure that Canada's youth are aware of the exciting careers in biotechnology, and that classroom outreach and alternative educational mechanisms are expanded and vigorously supported to strengthen "science culture" in Canada and, in particular, awareness of biotechnology.

Chapter 4

Market Access, Intellectual Property Rights and Regulation

1. (4.1)

NBAC recommends that Canadian trade negotiators 1) insist upon strict adherence to World Trade Organization disciplines by Canada's trading partners, 2) use vigorously, when appropriate, the trade remedy and dispute settlement procedures available under the General Agreement on Tariffs and Trade (1994), and 3) push energetically in the longer term for trade liberalizing solutions in which trade barriers are invoked on science-based risk assessment only.

2. (4.1.1)

NBAC recommends that federal departments with responsibility for the regulation of products of biotechnology examine, with their counterparts in Canada's major trading partners, ways of conducting joint reviews of product data packages and working towards mutual recognition of product regulatory reviews.

3. (4.1.2)

NBAC recommends that Canada's science-based regulatory system, together with agreements in place with Canada's trading partners, be used as the basis for a protocol on transboundary movement of Living Modified Organisms. Industry Canada and the Department of Foreign Affairs and International Trade should work to ensure that the Canadian negotiators strongly resist any attempts by other nations to make the Biosafety Protocol an additional regulatory burden on those countries that already have regulatory systems in place for these products.

4. (4.2)

NBAC recommends that Industry Canada work with the Department of Foreign Affairs and International Trade and actively participate in the follow-up to the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights and participate in the ad hoc working group to bring to the process the balanced perspectives of science, research, consumers and commercialization that the industry portfolio of the department represents.

5. (4.3.1)

NBAC recommends that Canada bring its regulations regarding Plant Breeders' Rights into line with the 1991 UPOV Convention and promote the ratification of that convention (or equivalent minimum plant breeder protection) among its trading partners.

6. (4.3.2)

NBAC recommends that the federal government study the intellectual property rules of Canada's major trading partners and, within the framework of the World Trade Organization, take the necessary steps to ensure that Canada's intellectual property rules provide the same support to commercialization as those of other signatories of the General Agreement on Tariffs and Trade (1994).

7. (4.3.2)

NBAC recommends that the Canadian Intellectual Property Office take note of industry concerns and not allow claims to naturally occurring "sequences with no legitimate utility" or "industrial applicability" that could unjustifiably block or restrict industrial development in Canada.

8. (4.3.2)

NBAC recommends that the Canadian Intellectual Property Office introduce an effective opposition procedure with a time limit of six months after grant, similar to procedures in Europe.

9. (4.3.3)

NBAC recommends that the federal government implement a fast-tracking system for patents filed in Canada that have identical claims to patents already issued in the United States and Europe. The Canadian Intellectual Property Office should allocate additional resources to the examination of patents thought to be too broad or controversial in their claims.

10. (4.4.1)

NBAC recommends that the federal government establish competitive Canadian target time lines for biotechnology product approvals through a process of comprehensive international benchmarking of regulatory approval times, and make this information public.

11. (4.4.2)

NBAC recommends that the regulatory system ensure officials build on their accumulated experience with the underlying science needed to assess risk, in order to reduce unnecessary information demands on industry. An annual assessment should be submitted to Treasury Board.

12. (4.4.4)

NBAC recommends that a streamlined, flexible and cooperative approach to regulatory approval of multidescriptor novel foods and drugs meeting health and safety standards be developed immediately by all relevant regulating departments.

13. (4.4.4)

NBAC recommends 1) that departments or special operating agencies regulating biotechnology establish external advisory panels composed of experts in the particular biosciences required to improve the regulators' capability to deal with the increasing number of products of biotechnology moving into commercialization, 2) that the expedited approval process currently in place be expanded and used in parallel with the regular system, and 3) that fees collected be reinvested in the regular approval system to make it more efficient.

14. (4.4.5)

NBAC recommends that the federal government ensure its regulations are equivalent to those of Canada's trading partners and that they do not put Canadian companies at a disadvantage when researching and/or bringing forward new products based on naturally occurring micro-organisms.

15. (4.4.6)

NBAC recommends that the federal government work with the provinces to ensure that the provincial power to regulate formularies does not become another barrier to trans-Canada trade in biopharmaceuticals.

16. (4.5)

NBAC recommends that 1) consistent and transparent public access routes (including Web sites) be developed for explicitly reporting and analyzing public comment received when proposing legislation and new or modified regulations, thereby closing the feedback loop to the public, and 2) the government release to the public, after taking into account commercial confidentiality agreements, plain-language versions of the regulatory decisions and the rationale supporting those decisions.

Chapter 5

The Social-ethical Context of Biotechnology

1. (5.5)

NBAC recommends that it evolve into an advisory body with a public role and a broader membership and mandate to include, in addition to its current terms of reference, the consideration of a socio-ethical framework for biotechnology policy.

NBAC recommends that the broadened advisory body catalyze a national conversation on biotechnology to ensure the systematic and consistent incorporation of public input on the socio-ethical dimension of biotechnology policy formulation.

Chapter 6

A Renewed National Biotechnology Advisory Structure

1. (6.0)

NBAC recommends that its current mandate be expanded to include a socio-ethical dimension and a public role, and that the new NBAC follow the Information Highway Advisory Council model in operation.

2. (6.1.3)

NBAC recommends that the new Advisory Council report to the Minister of Industry, who would be the focal point in Cabinet for biotechnology issues.

3. (6.1.7)

NBAC recommends that the Advisory Council meet annually with the interdepartmental coordinating body for the Canadian Biotechnology Strategy, to provide oversight of the Strategy's implementation.

4. (6.1.8)

NBAC recommends that the new Advisory Council be supported by a secretariat with a staff of four. The Council would be granted an annual operating budget of $1.5 million for five years as an allocation from within the Canadian Biotechnology Strategy, administered by Industry Canada.

Appendix 2

Preparation Process for NBAC *Sixth Report*

Minister challenges the NBAC: In March 1997, Industry Minister John Manley met with the National Biotechnology Advisory Committee and asked it to prepare the *Sixth Report* to address the competitiveness of Canada's biotechnology industry and issues of commercialization. Three academics, two CEOs and one patent lawyer among NBAC members volunteered to take a lead role in preparing the Report.

Policy Workshops: The six key authors held three policy working sessions in Ottawa. Authors established key themes, including international benchmarking, commercialization, the science and technology base, intellectual property protection and regulatory considerations, socio-ethical issues, and renewal of the advisory body structure and guided the policy analysis and elaboration of recommandations.

"Youth Team:" A youth team of some 14 graduate students was recruited to assist with background research. In the absence of a full-scale policy secretariat to underpin such an exercise, this national team of young future scientists provided energy, talent and enthusiasm to the tasks while gaining experience in biotechnology policy.

Conference calls across country and internationally: The Committee and its secretariat consulted over 100 national and international experts during the nine months' work. The Committee undertook a series of conference calls to experts in venture capital, tax policy, basic science, ethics, and other areas, to bring their experiences to bear on the deliberations.

Liaison with Canadian Biotechnology Strategy task group leaders: This Report was prepared during the renewal process for the Canadian Biotechnology Strategy (CBS). Minister Manley requested the *Sixth Report* as a key input to the process for a future strategy. The NBAC lead authors invited CBS task force leaders of the CBS Renewal to give input to the Committee and met to exchange perspectives on one occasion.

Ongoing issues for further exploration: The *Sixth Report* lists specific actions for the Minister's consideration. It also raises some issues that require further analysis, including developing sector-specific strategies for Canada and an enhanced ability to benchmark the performance of the industry. The discussion of socio-ethical dimensions of biotechnology and the elaboration of a socio-ethical framework for decision makers are other important action items.

Role in Canadian Biotechnology Strategy Renewal: As the existing policy advisory body to government on biotechnology, the NBAC proposes to play an active role in renewal of the Canadian Biotechnology Strategy. NBAC members, drawn from academia, industry, banking and law, offer to serve as effective agents in the deliberations during the renewal process.

Service During Transition: In the likelihood that the renewed Canadian Biotechnology Strategy will require a period of time prior to full implementation, the NBAC offers to continue to provide advice to government during the period of transition.

Secretariat: The NBAC Secretariat in the Bio-Industries Branch of Industry Canada served to implement the Committee's critical path for preparing of the 1998 *Sixth Report.*

Appendix 3

Glossary of Terms

AAFC	Agriculture and Agri-Food Canada
ACRE	Advisory Committee on Releases to the Environment
AIA	Advance Informed Agreement
AIDS	Acquired Immune Deficiency Syndrome
BHRC	Biotechnology Human Resource Council
BSWG	Biosafety Working Group
Bt	*Bacillus Thuringiensis*
CBS	Canadian Biotechnology Strategy
CCA	Capital Cost Allowances
CEPA	*Canadian Environmental Protection Act*
CGAT	Canadian Genome Analysis and Technology
cGMP	certified Good Manufacturing Practices
CIB	Canadian Institute of Biotechnology
CIPO	Canadian Intellectual Property Office
CMDF	Canadian Medical Discoveries Fund (Canada)
CSTG	Canadian Science and Technology Growth Fund
DCE	Danish Council of Ethics
DFAIT	Department of Foreign Affairs and International Trade
DHGHR	Declaration on the Human Genome and Human Rights
DNA	Deoxyribonucleic Acid
EC	Environment Canada
EGF	Epidermal Growth Factor
ELSI	Ethical, Legal and Social Implications
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organization
FTE	Full-time Equivalent
FY	Fiscal Year
GATT	General Agreement on Tariffs and Trade
GERD	Gross Domestic Expenditure on Research and Development
GDP	Gross Domestic Product
HGAC	Human Genetics Advisory Commission
HRDC	Human Resources Development Canada
HUGO	Human Genome Organization
IBAC	Industrial Biotechnology Association of Canada
IBC	International Bioethics Committee
IHAC	Information Highway Advisory Council
IC	Industry Canada
IP	Intellectual Property
IRAP	Industrial Research Assistance Program
LMO	Living Modified Organisms
LSVC	Labour-sponsored Venture Capital
MAB	Monoclonal Antibody
MELSI	Medical, Ethical, Legal and Social Implications

MRC	Medical Research Council of Canada
NBAC	National Biotechnology Advisory Committee
NBS	National Biotechnology Strategy
NCE	Networks of Centres of Excellence
NCIC	National Cancer Institute of Canada
NHMRC	National Health and Medical Research Council (Australia)
NIH	National Institutes of Health (US)
NRC	National Research Council of Canada
NSERC	Natural Sciences and Engineering Research Council of Canada
OCA	Office of Consumer Affairs
OECD	Organization for Economic Co-operation and Development
PBR	Plant Breeders' Rights
PMRA	Pest Management Regulatory Agency
POS	Protein, Oil and Starch
PTR	Patent Term Restoration
R&D	Research and Development
REBs	Research Ethics Boards
RIAS	Regulatory Impact Assessment Statement
RPMS	Regulatory Process Management Standards
SME	Small- and Medium-sized Enterprises
SOA	Special Operating Agency
SSHRC	Social Sciences and Humanities Research Council of Canada
TPC	Technology Partnerships Canada
TRIPS	Trade-related Intellectual Property
UMDI	University Medical Discoveries Inc. (Canada)
UNESCO	United Nations Educational Scientific and Cultural Organization
UPOV	International Union for the Protection of New Varieties of Plants
VIDO	Veterinary Infectious Disease Organization
WHO	World Health Organization
WTO	World Trade Organization

Appendix 4

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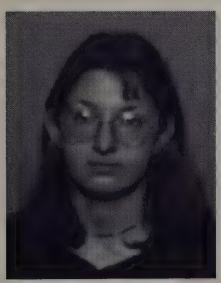
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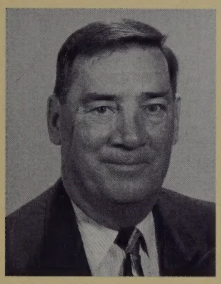

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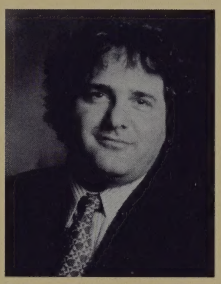

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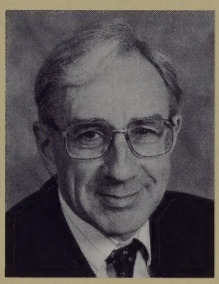

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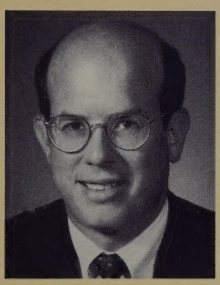

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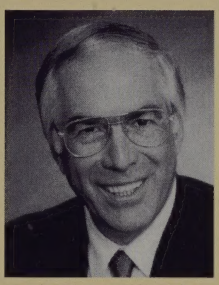

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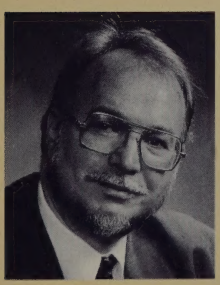

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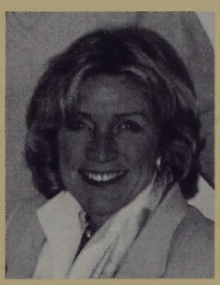

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